UNITED STATES DISTRICT COURT FOR THE
DISTRICT OF MASSACHUSETTS

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UNITED STATES OF AMERICA, et al.,
ex rel. JEFFREY J. BIERMAN,

CASE NO.: 05-10557 (EFH)

Plaintiff,

v.

SECOND AMENDED AND SUPPLEMENTAL COMPLAINT AND JURY DEMAND

ORTHOFIX INTERNATIONAL N.V., ORTHOFIX, INC., ORTHOLOGIC CORP., DJO INCORPORATED, REABLE THERAPEUTICS, INC., BIOMET INC., EBI, L.P., EBI HOLDINGS, INC, EBI MEDICAL SYSTEMS, INC., BIOELECTRON, INC., and SMITH & NEPHEW, INC.

LEAVE TO FILE GRANTED ON JUNE 9, 2010

Defendants.

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INTRODUCTION

Plaintiff/relator, Jeffrey J. Bierman, in the name of and on behalf of the United States of America, the State of California, the City of Chicago, the State of Delaware, the State of Florida, the State of Georgia, the State of Hawaii, the State of Illinois, the State of Indiana, the State of Louisiana, the State of Massachusetts, the State of Michigan, the State of Nevada, the State of New Hampshire, the State of New Mexico, the State of New York, the State of Tennessee, the State of Texas, the State of Virginia, and the District of Columbia, by his attorneys, Getnick & Getnick, as and for his complaint, alleges as follows:

1. As more fully alleged herein, this action arises out of a scheme or schemes to defraud the United States of America and other governments (referred to collectively herein as "the government") perpetrated by the defendants, commencing in or about 1993 and continuing to the date hereof. The defendants make false and fraudulent claims for payment, and/or make, use or cause to be made or used, false records and statements to get false claims paid to the government for certain items of durable medical equipment ("DME") used by patients in their homes, namely noninvasive osteogenesis stimulators (referred to herein for convenience simply as "osteogenesis stimulators"), covered by Medicare, Medicaid, and other federal and state purchasers of DME. Osteogenesis stimulators, which are also known as bone growth stimulators, are portable, non-sterile, battery-operated devices that use pulsed electromagnetic fields or ultrasound waves purportedly to promote bone growth in non-healing

fractures or to aid fusion after spinal surgery. Osteogenesis stimulators are relatively uncomplicated devices that cost about $50-$100 to manufacture. Their retail price is approximately $5,000 and the Medicare reimbursement is approximately $4,000. As a result of the submission of the false and fraudulent claims alleged herein, from 1998 to 2008 the defendants received more than $400 million under the Medicare program alone for osteogenesis stimulators and claims for the devices have increased by up to 500%.

2. The defendants are the sole manufacturers of osteogenesis stimulators in the United States and control the market for these devices.[1]

3. The allegations in this complaint are made in the present tense because the fraud is ongoing, but apply equally to completed conduct from in or about 1993 and continuing to the date hereof.

4. As further set forth in this complaint, the defendants, who manufacture, market, distribute and directly bill for the osteogenesis stimulators, submit claim forms to the government representing: (1) that the devices should be paid as purchase items, when in fact, and to the defendants' knowledge, they should have been billed and paid as rental items; and (2) that the devices were medically indicated and necessary for periods of time that were far in excess of the medical needs of patients, and in the vast majority of cases, the useful lifetime of the devices

[1] See below, paragraph 28.

themselves. The defendants sign express false certifications of such medical necessity when submitting claims to the government.

5. In furtherance of this fraudulent scheme, the defendants include false information on Certificates of Medical Necessity ("CMNs")[2] and, by misrepresenting regulatory and reimbursement aspects of the devices, cause physicians, their employees and/or clinicians to include false information on CMNs in order to deceive Medicare into paying for the devices as purchase items.

6. In addition, as further set forth herein, the claims are false because of the defendants' violations of the Medicare and Medicaid anti-kickback act, 42 U.S.C.1320a-7b(b) ("anti-kickback act") and the Medicare Durable Medical Equipment Supplier Standards, 42 U.S.C. §1395m(j)(1) and 42 C.F.R. 424.57, that came into effect on December 11, 2000 ("Supplier Standards") and their false certifications to Medicare of compliance therewith.

7. Between 1998 and 2008, Medicare purchased more than 120,000 brand new osteogenesis stimulators on behalf of patients. The vast majority of these devices currently are sitting idle in the homes of those patients, have been thrown out or otherwise disposed of. Osteogenesis stimulators are routinely listed for sale on eBay for as little as $50. Medicare, on the other hand, pays approximately

[2] A CMN for the type of device manufactured by Smith & Nephew, Inc., which uses ultrasound technology, was not required prior to January 1, 2007.

$4,000[3] for each new device, many of which have been used by patients for no more than a few months.

8. These acts constitute violations of the federal False Claims Act, 31 U.S.C. § 3729, *et. seq.* ("FCA"), and numerous state and city equivalent statutes.[4] The FCA provides, *inter alia*, that any person who knowingly presents and/or causes to be presented a false or fraudulent claim for payment, or who knowingly makes, uses or causes to be made or used, a false record or statement material to a false or fraudulent claim liable for a civil penalty of up to $11,000 for each claim, plus three times the amount of the damages sustained by the Government.[5] The FCA

[3] $4,000 is the approximate cost to Medicare (exclusive of the 20% patient co-payment) of electromagnetic devices reimbursed under E0747 and E0748. Ultrasonic devices are reimbursed under E0760 and the approximate cost to Medicare is $3,400.

[4] As set forth below, the defendants' acts constitute violations of the California False Claims Act, Cal. Gov't Code §§ 12650-12655; the Delaware False Claims and Reporting Act, 6 Del. C. §§ 1201 et seq.; the District of Columbia Procurement Reform Amendment Act, D.C. Code Ann. §§ 2-308.13-21; the Florida False Claims Act, Fla. Stat. Ann. §§ 68.081-092; the Georgia State False Medicaid Claims Act, Ga. Code Ann. §§ 49-4-168 et seq.; the Hawaii False Claims Act, Haw. Rev. Stat. §§ 661-21-29; the Illinois Whistleblower Reward and Protection Act, 740 Ill. Comp. Stat. §§ 175/1-8; the Indiana False Claims and Whistleblower Protection Act, IC 5-115.5 et seq.; the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. 46:437.1-14; the Massachusetts False Claims Act, Mass. Gen. L. Ch. 12, §§ 5B et seq.; the Michigan Medicaid False Claims Act, MCL §§ 400.601 et seq.; the Nevada False Claims Act, Nev. Rev. Stat. §§ 357.010 et seq.; the New Hampshire Medicaid Fraud and False Claims Act, RSA §§ 167.58 et seq.; the New Mexico Medicaid False Claims Act, N.M. Stat. Ann. §§ 27-12-1 et seq.; the New York False Claims Act, N.Y. State Fin. Law §§ 187-194; the Tennessee Medicaid False Claims Act, Tenn. Code Ann. §§ 71-5-182 et seq.; the Tennessee False Claims Act, Tenn. Code Ann. §§ 4-18-101 et seq.; the Texas Medicaid Fraud Prevention Law, Tex. Hum. Res. Code Ann. §§ 36.001 et seq.; the Virginia Fraud Against Taxpayers Act, Va. Code Ann. §§ 8.01-216.3 et seq.; and the Chicago False Claims Act, Chicago Municipal Code Ch. 1-21 et seq.

[5] The FCA was amended on May 20, 2009. Previously, the FCA provided, in relevant part, that any person who knowingly presents and/or causes to be presented to the United

allows any person discovering a fraud perpetrated against the Government to bring an action for himself and for the Government and to share in any recovery. The complaint in an FCA action is filed under seal for 60 days, or for such extensions of that period of time as the court approves upon the Government's motion (without service on the Defendant), to enable the Government (1) to conduct its own investigation without the defendant's knowledge and (2) to determine whether to join in the action.

9. The plaintiff/relator, Jeffrey J. Bierman, ("the relator") is the co-owner of a 25-person company located in Missouri that provides surgical and DME non-coding medical billing services and compliance programs to doctors, hospitals, nursing homes and other health care providers. 40% of the relator's business relates to DME. In 2001, the relator's company was recognized by the Health Care Financing Administration (now known as the Centers for Medicare and Medicaid Services ("CMS")) as a Gold Star Preferred Billing Service.

10. The relator seeks to recover treble damages and civil penalties in the name of the United States for the violations alleged herein, amounting to hundreds of millions of dollars.

States a false or fraudulent claim for payment, or who knowingly makes, uses or causes to be made or used, a false statement to get a false or fraudulent claim paid, is liable for a civil penalty of up to $11,000 for each claim, plus three times the amount of the damages sustained by the Government.

JURISDICTION AND VENUE

11. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and 28 U.S.C. § 1367. In addition, 31 U.S.C. § 3732(a) specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§ 3729 and 3730, and 31 U.S.C. § 3732(b) specifically confers jurisdiction on this Court over the state law claims asserted in this Complaint.

12. This Court has personal jurisdiction over the defendants pursuant to 31 U.S.C. § 3732(a) because that section authorizes nationwide service of process and because the defendants have minimum contacts with the United States. Moreover, at least one defendant can be found in, resides, or transacts business in this District.

13. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a) because at least one defendant can be found in, resides, or transacts business in this District.

PARTIES

14. The relator is a citizen of the United States and a resident of the state of Missouri. He is an original source of the information contained herein within 31 U.S.C. § 3730(e)(4).

15. Defendant Orthofix International N.V. is a publicly-traded company incorporated in Curacao, Netherlands Antilles, with its corporate headquarters located at 7 Abraham de Veerstraat, Curacao. Orthofix International N.V. is a multinational corporation principally involved in the design, development, manufacture, marketing and distribution of medical equipment, principally for the orthopedic products market.

16. Defendant Orthofix, Inc. is a wholly-owned subsidiary of Orthofix International N.V.. Orthofix, Inc. is located at 1720 Bray Central Drive, McKinney, TX 75069. Orthofix, Inc. manufactures, markets and distributes a broad range of minimally invasive surgical and non-surgical products for orthopedic applications. Amongst other products, Orthofix manufactures, markets, distributes and directly bills Medicare for the Spinal Stim, Physio-Stim and Cervical Stim osteogenesis stimulators. Defendants Orthofix International N.V. and Orthofix, Inc. are collectively referred to herein as "Orthofix."

17. Defendant Orthologic Corp. ("Orthologic") is a publicly-traded company located at 1275 West Washington St., Tempe, AZ 85281. Prior to November 2003, Orthologic Corp. manufactured, marketed, distributed and directly billed Medicare for the Spinalogic and OL1000 Bone Growth Stimulators. On November 26, 2003 Orthologic Corp. sold all of its bone growth stimulator business to dj Orthopedics, Inc. On May 30, 2006, dj Orthopedics, Inc.

announced that it had changed its name to DJO Incorporated. The allegations contained herein do not apply to Orthologic after November 26, 2003.

18. Defendant DJO Incorporated is a global medical device company specializing in rehabilitation and regeneration products for the non-operative orthopedic and spine markets located at 1430 Decision Street, Vista, California. DJO Incorporated manufactures, markets, and directly bills for the OL1000 and Spinalogic bone growth stimulators through its CMF Bone Growth Stimulators Division. DJO Incorporated was a publicly traded company until November 2007 when it was acquired by defendant Reable Therapuetics, Inc.

19. Defendant Reable Therapeutics, Inc., is a diversified orthopedic device company that develops, manufactures and distributes a range of orthopedic products located at 9800 Metric Blvd., Austin TX 78758. Reable Therapeutics is a leading distributor of electrical stimulation and other orthopedic products. In November 2007 Reable Therapeutics, Inc. completed a merger transaction pursuant to which an affiliate of Reable Therapeutics, Inc., acquired all outstanding shares of DJO Incorporated and Reable Therapeutics, Inc. announced its intention to change its name to DJO Incorporated.

20. Defendants DJO Incorporated and Reable Therapeutics, Inc. are referred to collectively herein as “DJO,” except that the allegations herein do not apply to

DJO Incorporated prior to November 26, 2003 and do not apply to Reable Therapeutics, Inc. prior to November 2007.

21. Defendant Biomet, Inc. and its subsidiaries design, manufacture and market products used primarily by musculoskeletal medical specialists in both surgical and non-surgical therapy, including osteogenesis stimulators. Prior to September 2007, Biomet, Inc. was publicly traded company located at 56 Bell Drive, Warsaw, Indiana 46581. It is now a privately held corporation located at the same address. Biomet, Inc. acquired EBI, L.P. in 1988.

22. Defendant EBI, L.P. is a wholly owned subsidiary of Biomet, Inc. located at 100 Interpace Parkway, Parsippany, New Jersey 07054. EBI, L.P. designs, manufactures, markets, distributes and directly bills for the SpinalPak and OrthoPak bone growth stimulators and other products used by orthopedic medical specialists in surgical and non-surgical therapy.

23. Defendant EBI Holdings, Inc., the general partner of EBI, L.P., is a Delaware corporation with its principal place of business at 100 Interpace Parkway, Parsippany, New Jersey 07054.

24. Defendant EBI Medical Systems, Inc., the sole limited partner of EBI, L.P., is a Delaware corporation with its principal place of business at 100 Interpace Parkway, Parsippany, New Jersey 07054.

25. Defendant Bioelectron, Inc. was purchased by EBI, L.P. in September 2000 and is a wholly owned subsidiary of EBI, L.P. Bioelectron, Inc. was a privately held corporation located at 25 Commerce Drive, Allendale, NJ 07401. As a result of the acquisition of Bioelectron Inc., EBI, L.P. added to its product line the SpinalPak and the OrthoPak bone growth stimulators.

26. Defendants Biomet, Inc., EBI, L.P., EBI Holdings, Inc., EBI Medical Systems, Inc., and Bioelectron, Inc. are referred to collectively herein as "EBI."

27. Defendant Smith & Nephew, Inc. ("Smith & Nephew") is located at 1450 E. Brooks Road, Memphis, TN 38116. Amongst numerous other products, Smith & Nephew manufactures, markets and directly bills Medicare for the Exogen Bone Healing System, a bone growth stimulator that transmits a low intensity ultrasound signal to the fracture site through coupling gel. Smith & Nephew is the main operating company in the United States of Smith & Nephew plc, a company incorporated under the laws of England and Wales and located at 15 Adam Street, London WC2N 6LA. The Exogen Bone Healing System has been covered by Medicare since 2001. The allegations herein do not apply to Smith & Nephew prior to 2001.

SUMMARY OF FRAUDULENT SCHEME

28. The defendants in this action are the sole manufacturers of noninvasive osteogenesis stimulators in the United States and represent 100% of the market for the devices. In a letter to the FDA dated August 17, 2005, EBI, DJO and Orthofix told the FDA: "Collectively, we … are responsible for 100% of the electrical/electromagnetic external BGS [bone growth stimulator] market." (FDA Docket 2005P-0121/CCP1; Comments in Opposition to the Reclassification of External Bone Growth Stimulators.) Smith & Nephew is the only manufacturer of ultrasonic osteogenesis stimulators in the United States. Therefore, the defendants collectively represent 100% of the market for noninvasive osteogenesis stimulators and control the market in the United States.

29. Osteogenesis stimulators are light weight, battery operated devices worn externally by patients with non-healing bone fractures for a few hours each day. They purport to promote bone growth and healing by inducing weak electromagnetic fields or ultrasonic waves in the bone. They were approved by the FDA in 1979 and are covered by Medicare for non-healing fractures and as an adjunct to spinal surgery under three HCPCS codes, E0747 (electromagnetic, long bone), E0748 (electromagnetic, spinal) and E0760 (ultrasonic). (See further, paragraphs 55-56 below.)

30. The length of use required to achieve bone healing varies from patient to patient. According to clinical studies (see paragraphs 71-75 below), most patients use the devices for periods of between 3 and 6 months and some use them for as little as 2 months. The physician monitors the patient's progress from the commencement of therapy and determines when either bone healing has occurred or the device appears to have failed. In either event, its use is then discontinued.

31. The electromagnetic devices now manufactured by defendants Orthofix, DJO and EBI (and previously manufactured by Orthologic) contain a computer chip that is programmed to cause the device to automatically deactivate after 9 months of regular use. The ultrasonic device manufactured by defendant Smith & Nephew does not have the same deactivation feature. However, the single power source for this device is a non-replaceable and non-rechargeable lithium battery with a life of a minimum of 150 daily treatment periods (five months).

32. The clinical reasons for this deactivation feature have not been explained by the manufacturers. In FDA filings the manufacturers state that, while the long term effects of exposure to electromagnetic fields are not known, no adverse affects on health have been identified. The initial Premarket Approval Application for noninvasive osteogenesis stimulators submitted by defendant EBI and approved by the FDA in 1979 states: "Routine clinical observations over 5 years indicate this device causes no known risks."

33. Medicare pays for osteogenesis stimulators on a monthly rental or purchase basis according to a fee schedule. Medicare will pay for monthly rental up to the fee schedule purchase price, at which point the rental payments stop. While the fee schedule varies state by state, the purchase price consistently is approximately 10 times more than the rental price (see paragraph 58 below). Therefore, a device would have to be used for a period of 10 months or more for the accrued rental payments to reach the purchase price. However, since the devices typically are used for periods of between 3 and 6 months, and because the E0747 and E0748 devices deactivate after 9 months, the monthly rental charges would never reach the purchase price. In most cases the monthly rental payments for the actual time used would be considerably less than the purchase price.

34. The defendants nonetheless routinely bill the devices to Medicare and others as purchase items. The defendants claim and receive from Medicare approximately $4,000[6] up front for each osteogenesis stimulator prescribed and have collected more than $400 million under the Medicare program since 1998. As set forth above, each of the manufacturers has its own billing personnel who directly bill Medicare, other insurers and patients.

35. Medicare requires that a CMN be filed with each claim under E0747, E0748 and E0760. A CMN was not required for claims under E0760 prior to January 1, 2007. The allegations in paragraphs 36 – 39 below do not apply to the

[6] See footnote 3 above.

manufacturer of the E0760 device, Smith & Nephew, for the period prior to January 1, 2007.

36. The defendants mislead physicians and their clerical staff into filling out CMNs containing a code indicating that the devices are medically necessary for the patient's lifetime or for periods of time that exceed the medical needs of the patient and/or the devices' useful life. Other evidence suggests that the defendants may even by-pass physicians altogether and simply make some or all of the medical necessity certifications themselves, contrary to Medicare rules and federal laws. (See below, paragraphs 79 and 88.)

37. The CMN requires the physician to state how long he/she expects the patient will need to use the device. The CMN gives the physician the option of specifying a number of months or entering the code "99," indicating that the patient will need the device for life. (See paragraph 70 below.)

38. In the vast majority of cases, the "medical necessity" section of the CMN is completed by the physician's clerical assistant and the CMN is signed off by the physician. These clerical assistants typically rely on the equipment suppliers' representatives for advice about how the CMN should be completed in order to ensure that claims will be processed and paid by Medicare and other insurers. Equipment suppliers are permitted or required, under Medicare rules, to complete

some sections of the CMN (although not the "medical necessity" section) and routinely do so. (See paragraph 68 – 69 below.)

39. In order to mislead physicians and their clerical staff into filling out CMNs supporting the defendants' claims for payment for the devices as purchase items, the defendants routinely instruct them to include the code "99" on the CMN or otherwise specify a number of months that will support payment for the item as a purchase.

40. The defendants routinely claim that the devices have been designated by the FDA as devices that are disposable and can only be used by one patient. Often citing the fact that the devices deactivate after a period of months, the defendants routinely claim that the devices "cannot" be reused and must be billed as a purchase, apparently on the basis that the concept of a single-use device is incompatible with rental.

41. Medical devices that can only be used by one patient are referred to in FDA parlance as "Single Use Devices" ("SUDs"). SUD designation is not an FDA requirement but is applied at the discretion of the device manufacturer. Further, many SUDs can be and are in fact reprocessed, subject to compliance with FDA reprocessing rules.

42. It is well-recognized in the health care profession that SUDs frequently are misdesignated as such by manufacturers in order to boost profits. In a June 2000 report on the reprocessing of SUDs, the GAO observed:

> "Many health care professionals believe that some SUDs can be reused. They told us they distrust the single-use label for some devices because (1) FDA cannot require manufacturers to support the designation of a device as single-use; (2) they perceive that manufacturers have an economic incentive to market devices as single-use that could just as well be sold as reusable; and (3) FDA's approval requirements for SUDs are less extensive than those for reusable devices …
>
> On occasion, manufacturers have contributed to the sense that compliance with the single-use label is not always necessary . . . [For example,] a major manufacturer of pulse oximeter sensors, essentially offer[s] to sell 'remanufactured' sensors for reduced prices to health care institutions that return their used single-use sensors to the company . . . ." (emphasis added)

43. In fact, the alleged single-use designation for osteogenesis stimulators is economically and not clinically motivated. The patient safety reasons, if any, for limiting use to a single patient are obscure and have not been explained by the manufacturers. The devices are non-sterile, they are worn externally, often over clothing, and any electrodes intended to be attached to the skin are disposable. As set forth above (paragraph 32), the clinical rationale for the deactivation feature likewise has not been explained by the manufacturers. In fact, this feature serves no other purpose than to prevent re-use. (See paragraph 44 below.) The alleged single use designation and the deactivation feature are designed to generate additional profits for the manufacturers and to prevent the development of a secondary market -- in particular, a secondary rental market -- for osteogenesis stimulators.

44. A 1993 newspaper article reported on the efforts of one patient to give his Orthopak bone growth stimulator to another user when the patient's bone gap healed after 4 months. His doctor replied that "the FDA wouldn't allow it to be used on more than one patient." His doctor also noted that "the logic behind the one-use rule eludes him. It's not as though the device gets contaminated while in use." The article continues:

> "Ron McNeill, sales and marketing director for Bioelectron, said the company doesn't plan to ask the FDA to allow multiple-patient use for two reasons: It is concerned about inappropriate use, and it would lose its profit margin.
>
> 'We think we're already saving an individual money,' McNeill said.
>
> To prevent reuse, he said, the company installs a computer chip that automatically shuts the device down after 200 days of use."

Carol Gentry, "Useful Device Sits on Shelf," *St. Petersburg Times*, November 29, 1993, p. B1. (emphasis added)

45. Further, like the manufacturer of pulse oximeter sensors referred to in the GAO's report referenced above, at least one defendant admits that its osteogenesis stimulators can be, and are in fact, reprocessed. As further set forth in paragraph 83 below, an EBI representative stated in 2003 that EBI will take used devices back, refurbish them and give them to indigents.

46. Further, in some Adverse Event Reports filed with the FDA, three of the manufacturers apparently state that their bone growth stimulators are not single use devices. For example, such reports were filed by Smith & Nephew on June

30, 2003, by Orthofix on April 20, 2007, and by EBI on March 2, 2007. The Smith & Nephew filing states that the "type of device usage" is "reuse."

47. The alleged single-use device designation thus is no more than a ploy to mislead physicians, their staff and others into believing that Medicare will not process payment for the devices unless they are billed as a purchase, and to cause physicians, their staff and others to include false information on CMNs supporting the manufacturers' claims for the devices as a purchase.

48. Whether or not osteogenesis stimulators are designated as single-use devices, they should never be billed to Medicare as a purchase and should always be billed as a rental. This is because: (a) Medicare has designated osteogenesis stimulators as rental OR purchase items; (b) the period of medical necessity will never be known in advance of treatment, but will be determined in the course of treatment by the physician on the basis of x-rays of the patient's progress (and so billing should occur on a month-to-month basis); (c) Medicare will pay for the devices on a rental basis for as long as the devices are medically necessary, up to the cost of the purchase price; (c) clinical studies show that patients use the devices for approximately 3 to 6 months; (d) as to E0747 and E0748 devices, the period of medical necessity for a single device could never exceed 9 months (since the devices are programmed to deactivate after 9 months); and (e) the purchase price is equal to 10 months of rental, one month more than the useful life of the E0747

and E0748 devices, and four months longer than the usual maximum period of use for all devices.

49. As further set forth in paragraphs 117 - 118 below, commencing in or about December 2000, the defendants routinely violate the Supplier Standards, including Supplier Standard No. 5, 42 C.F.R. § 424.57(c)(5), effective December 11, 2000, requiring that suppliers "advise beneficiaries that they may either rent or purchase inexpensive or routinely purchased durable medical equipment." Compliance with the Supplier Standards is a precondition for payment by Medicare and a precondition for eligibility in the Medicare program. See certification in Medicare Enrollment Application (paragraph 118 below) and 42 C.F.R. 424.57(d).

50. Compliance with Supplier Standard No. 5 is fundamental to Medicare's reimbursement model for osteogenesis stimulators. The Medicare program seeks to empower beneficiaries, who are responsible for a 20% copayment, to make informed decisions about whether rental is cheaper than purchase consistent with their medical need. Requiring suppliers to advise beneficiaries of the rental option is a necessary component of this process. The defendants' non-compliance with Supplier Standard No.5 defrauds not only Medicare but Medicare patients who are forced to bear the burden of a copayment of approximately $800 for a device that they may use for only a few months and that they should have been afforded the opportunity to rent for a fraction of this amount.

51. While Supplier Standard No. 5 became effective in December 2000, it was not a novel concept but a codification of requirements that had been in place for at least a decade. According to Medicare, "[t]his standard is merely a reinforcement of … the statute, at section 1834(a)(7) of the [Social Security] Act referring to payment for other items of DME. Since it is the beneficiary's decision whether to rent or purchase items, the supplier must explain the ramifications of this decision to the beneficiary at the required points in time to help the beneficiary make an informed decision." 65 Fed. Reg. 60370 (October 11, 2000).

52. As further set forth in paragraph 123 below, from at least 2005 to the present, the defendants conduct their business and furnish osteogenesis stimulators in violation of the anti-kickback act, under which it is illegal to offer, pay, solicit or receive anything of value as an inducement to generate business payable by Medicare or Medicaid.

53. As further set forth in paragraphs 117-123 below, in order to receive payment by Medicare, the defendants certify in their applications for Medicare billing privileges ("Medicare Enrollment Application"), which are renewed every three years, that they are will abide by applicable Medicare laws, regulations and program instructions (including meeting and maintaining the Supplier Standards) and that they understand that payment by Medicare is conditioned upon compliance therewith (including compliance with the anti-kickback act). As a

result of the defendants' violations of the Supplier Standards, the defendants' certifications in their Medicare Enrollment Applications are false, and all claims made to Medicare by the defendants for osteogenesis stimulators are false. As a result of the defendants' violations of the anti-kickback act, the defendants' certifications in their Medicare Enrollment Applications are false, and all claims made to Medicare by the defendants and third party suppliers for osteogenesis stimulators arising from such violations are false.

54. In addition or alternatively, since Medicare and Medicaid do not cover items or services that are provided because of illegal inducements, and since the defendants violate the anti-kickback act as set forth in paragraph 123 below, all claims for payment for those items and services arising from such violations are false.

MEDICARE REIMBURSEMENT FOR OSTEOGENESIS STIMULATORS

55. Medicare coverage for noninvasive electrical stimulation for fracture healing has been in effect since September 15, 1980. Initial coverage was limited to nonunion of long bone fractures, failed fusion and congenital pseudarthroses. In 1996 coverage was expanded to include the use of both non-invasive and invasive osteogenic stimulation as an adjunct to spinal fusion surgery. In 2001 coverage was expanded to include osteogenesis stimulation using ultrasound (as distinct from electromagnetic currents) for the treatment of non-union fractures. In 2005

coverage was expanded to include the use of electromagnetic stimulation in the cervical area of the spine.

HCPCS Codes and Coverage Criteria

56. Suppliers making claims for reimbursement for DME identify the items on claim forms using unique codes, known as HCPCS codes. Osteogenesis stimulators are reimbursed by Medicare under the HCPCS codes E0747, E0748 and E0760, as follows:

    a. E0747: Osteogenesis stimulator, electrical, non-invasive, other than spinal applications.

    b. E0748: Osteogenesis stimulator, electrical, non-invasive, spinal applications.

    c. E0760: Osteogenesis stimulator, low intensity ultrasound, non-invasive.

57. Medicare coverage criteria for osteogenesis stimulators are as follows:

    a. E0747:

        i. Nonunion of a long bone fracture where fracture healing has ceased for more than three months[7] prior to starting treatment.

        ii. Failed fusion of a non spinal joint where a minimum of nine months has elapsed since the last surgery.

        iii. Congenital pseaudoarthrosis.

[7] Prior to 2000, an E0747 device was covered for nonunion of a long bone fracture where fracture healing had ceased for more than nine months prior to starting treatment. This coverage change was made after intensive lobbying by Orthofix and EBI.

b. E0748

   i. Failed spinal fusion where a minimum of nine months has elapsed since the last surgery.

   ii. Following a multilevel spinal fusion surgery.

   iii. Following a spinal fusion surgery where there is s history of a previously failed spinal fusion at the same site.

c. E0760 (ultrasound)

   i. Nonunion of a fracture, and documented failure of at least one open surgical intervention for treatment of the facture.

   ii. The fracture cannot be of the skull or vertebrae or tumor-related.

See: Medicare Coverage Issues Manual, Section 35-48.

Medicare Fee Schedule

58. Osteogenesis stimulators are reimbursed by Medicare on either a purchase or monthly rental basis. While the Medicare fee schedule payments vary slightly from one state to another, the purchase price consistently is approximately 10 times more than the rental price. For example, in Maryland, the fee schedule purchase price for a new E0748 device is $4,085.24 and the rental price is $408.52. In Arkansas, the fee schedule purchase price for a new E0748 device is $4,126.06 and the rental price is $412.62. In Pennsylvania, the fee schedule purchase price for a new E0747 device is $3,963.48 and the rental price is $396.32. Hawaii has slightly higher pricing: new E0747 devices are $4,412.06

and rental E0747 devices are $442.56. Nationwide, the approximate purchase price of devices reimbursed under E0747 and E0748 is $4,000 and the approximate rental price is $400. The approximate purchase price of E0760 devices is approximately $3,400 and the approximate rental price is $340.

Medicare Reimbursements from 1998 to 2008

59. As further set forth in this complaint, osteogenesis stimulators have been billed by the defendants without exception as purchase items. Medicare reimbursements between 1998 and 2008 (the years for which data is currently available to the relator) exceed $429 million. From 2000 through and including 2007, E0747 and E0748 were in the Top 200 Level II HCPCS Codes, ranked according to total annual reimbursements. Reimbursements under E0748 between 1999 and 2008 grew by more than 500%.

	Code: E0747 (not spinal)		**Code: E0748 (spinal)**	
Year	**Charges**	**No. of devices**	**Charges**	**No. of Devices**
2008	Not Published*	Not Published	$60,280,307	15,493
2007	$18,298,747	5,018	$50,544,311	13,345
2006	$16,580,093	4,544	$40,877,558	10,795
2005	$18,123,845	5,217	$42,387,924	11,492
2004	$18,325,435	5,329	$30,632,692	8,572
2003	$17,166,052	5,085	$25,520,001	7,290
2002	$13,074,171	3,888	$19,923,083	5,724
2001	$9,412,826	2,832	$13,594,422	3,919
2000	$8,769,299	2,738	$11,232,505	3,361
1999	Not Published	Not Published	$7,897,115	2,364
1998	$6,427,197	2,024	Not Published	Not Published
TOTAL	$126,177,665	36,675	$302,889,918	82,355

Source:
http://www.cms.hhs.gov/MedicareFeeforSvcPartsAB/04_MedicareUtilizationforPartB.asp#TopOfPage (last visited April 29, 2010.)

* Note : Reimbursement data for items that are not in the Top 200 Level II HCPCS Codes are not published. The E0760 device was not in the Top 200 for the time period 2001 through 2008 and was not covered by Medicare prior to 2001.

Medicare Reimbursement Rules

60. Reimbursement for DME, prosthetics, orthotics and supplies ("DMEPOS") is established by Medicare fee schedules. The fee schedule classifies most DMEPOS into one of six categories (42 U.S.C. §1395m (a)):

    a. Inexpensive or other routinely purchased;

    b. Items requiring frequent and substantial servicing;

    c. Customized items;

    d. Other prosthetic and orthotic devices;

    e. Capped rental items;

    f. Oxygen and oxygen equipment

61. Osteogenesis stimulators are classified in the "inexpensive or other routinely purchased" category, also known as Category 1. Payment for inexpensive and routinely purchased items is made on a monthly rental basis or in a lump sum amount for purchase of the item based on the applicable fee schedule amount. (42 C.F.R. §414.220(b)(1).) The total amount of payments made for an item cannot exceed the purchase price stated in the fee schedule. (42 C.F.R. §414.220(b)(3).)

Medicare will pay for monthly rental up to the fee schedule purchase price, at which point the rental payments stop. See, e.g., Region B DMERC Supplier Manual, Chapter 14 – Payment Policy, page 11 of Revision 32, December 2002.

62. All claims for reimbursement must be justified by medical need. "No payment may be made under Part A or Part B for any expenses incurred for items or services … which are not reasonable or necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member". (42 U.S.C. §1395y(a)(1)(A).) Claims for reimbursement cannot exceed the medical needs of the patient and must be economical. "It shall be the obligation of any health care practitioner and any other person (including a hospital or other health care facility, organization, or agency) who provides health care services for which payment may be made (in whole or in part) under this Act, to assure, to the extent of his authority, that services or items ordered or provided by such practitioner or person to beneficiaries and recipients under this Act— (1) will be provided economically and only when, and to the extent, medically necessary …" 42 U.S.C. §1320c-5(a). A medically necessary service is one that, amongst other things, is "appropriate, including the duration … that is considered appropriate for the service, in terms of whether it is furnished in accordance with accepted standards of medical practice …[and is] one that meets, but does not exceed, the patient's medical need." Medicare Program Integrity Manual, Chapter 13, § 13.5.1. (emphasis added).

Procedure for Making Claims

63. In order to make a claim for payment under E0747, E0748 and E0760,[8] the supplier must submit to CMS a Health Insurance Claim Form, FORM CMS-1500 ("1500 Form") and a Certificate of Medical Necessity ("CMN").

The 1500 Form

64. When completing the 1500 Form, the supplier is required to indicate by the use of a "modifier" whether the item is being billed as a rental item (signified by the modifier RR), a purchase of new equipment (signified by the modifier NU) or a purchase of used equipment (signified by the modifier UE). The modifier appears immediately after the HCPCS code in Box 24D of the 1500 Form.

65. The supplier also must include the charge for the items or services in Box 24F of the 1500 Form.

66. When submitting the 1500 Form, the supplier is required to make an express written certification that "the services shown on the form were medically indicated and necessary to the health of the patient."

[8] A CMN was not required for E0760 devices prior to January 1, 2007.

The CMN

67. The CMN must be signed by the ordering physician, a physician employee, or a non-physician clinician (such as a home health nurse or physical therapist). This signature appears in Section D of the CMN and attests *inter alia* that the medical necessity information in the CMN is true, accurate and complete.

68. Section C of the CMN is headed: "Narrative Description of the Equipment and Cost." This section must be completed by the supplier and include a description of the item, the supplier's charge and the Medicare Fee Schedule Allowance for the item.

69. Section B of the CMN is headed: "Information in this Section May Not Be Completed by the Supplier of the Items/Supplies." Section B contains "medical necessity" information and must be completed by the ordering physician, a physician employee, or a non-physician clinician (such as a home health nurse or physical therapist). 42 U.S.C. 1395m(j)(2)(A) provides civil money penalties for distributing to physicians and/or beneficiaries CMNs containing information other than the identification of the supplier and beneficiary and the description, product code, fee schedule amount and supplier's charge for the equipment.

70. Section B provides for the physician, physician employee or clinician to indicate the length of time the physician expects the patient to require use of the ordered

item by placing a number in the section marked: "est. length of need (# of months)." The CMN also provides for the physician to enter the code number "99" in that section if the physician expects that the patient will require the item for the duration of his/her life. This is a standard code used on CMNs for numerous medical devices including seat lift mechanisms, hospital beds and wheel chairs, which can be and frequently are needed by patients for life. As set forth above, however, osteogenesis stimulators are healing devices and could never be needed by a patient for life.

CLINICAL STUDIES

71. According to clinical studies, most patients use osteogenesis stimulators for periods of between 3 and 6 months. Sometimes healing occurs after only 2 months.

72. In a review article published in 2004, Roy K. Aaron, MD; Deborah McK. Ciombor, PhD, and Bruce J. Simon, PhD., *Treatment of Nonunions With Electric and Electromagnetic Fields*, Clinical Orthopaedics & Related Research, (419):21-29, February 2004, the authors noted the healing times in studies using IC (inductive coupling) and CC(capacitive coupling), both noninvasive techniques using electrical currents to promote bone growth, as follows: "One study of 127 delayed and non-unions of the tibial diaphysis reported an 87% union rate with a median healing time of 5.2 months. Another study showed a success rate of 64%

of 149 patients with the majority healing in 3 to 6 months after treatment. Using CC techniques, 77% of 22 non-unions healed with a mean healing time of 23 weeks [5.75 months]."

73. Other studies include:

a. S.A. Satter, M.S. Islam, K.S. Rabbani, and M.S. Talukder, *Pulsed electromagnetic fileds for the treatment of bone fractures,* Bangladesh Med. Res. Counc. Bull. 25, 6-10 (1999): 19 patients received low amplitude PEMF on non-union or delayed union of long bones. Within an average treatment period of 14 weeks (i.e., 3.5 months), 11 of the 13 patients who completed the treatment schedule had successful bone healing.

b. R. I. Abeed, M. Naseer and E.W. Abel, *Capacitively Coupled Electrical Stimulation Treatment: Results from Patients with Failed Lone Bone Fracture Unions.* J. Orth. Trauma 1998; 12 (7): 510-3: 16 patients with nonunited fractures of the long bone were treated with capacitively coupled electrical stimulation. If healing had not occurred by 30 weeks (i.e., 7.5 months) the device was removed and considered to have failed. 11 of the 16 patients achieved union at an average of 15 weeks (i.e., 3.75 months) of stimulation.

c. P. Zmora-Navas, V.A., Borras, L.R. Antelo, A. Saras, Jr., and M.C. Pena Reina, *Electrical stimulation of bone non-union with the presence of a gap*, Acta Orthop. Belg. 61, 169-176 (1995): 22 established non-unions were treated with capacitively-coupled electrical signal. After an average of 26 weeks (i.e., 4.5 months) of treatment, solid bone union was achieved in 72.2% of cases.

d. C. Andrew L. Basset, MD, ScD; Sharon N. Mitchell, RN, and Sawnie R.Gaston, MD, *Pulsing electromagnetic field treatment in ununited fractures and failed arthrodeses*, JAMA. 247(5):623-8, 1982. 1,028 patients were studied for 8 years. The average time of use was 5.5 months. The authors noted: "Whether such a long time of coil use is necessary to produce a satisfactory end result is open to question … Generally, a thorough review of 'slow healers' of technical and patient cooperation patterns, two to four months after PEMF treatment has been initiated, will identify components that, when corrected, should produce a "coil effect" (stage 1 healing) within two months. If no procedural problems can be identified and there is no progress at six months, operative intervention should be given strong consideration." (at page 627)

e. Holmes, G. B. Jr. Treatment of delayed unions and nonunions of the proximal fifth metatarsal with pulsed electromagnetic fields. Foot Ankle Int, 1994 Ott; 15 (10): 552-556: 9 delayed unions and nonunion of the

proximal fifth metatarsal were treated with PEMF. All fractures healed in a mean time of 4 months (range 2-8 months). Those fractures treated with both pulsed electromagnetic fields and a non weight-bearing cast healed in a mean time of 3 months (range 2-4 months).

74. The period of use, therefore, rarely exceeds 6 months. Indeed, defendant Orthofix operates a money-back program for its Cervical-Stim and Physio-Stim devices if fusion does not occur within 6 months:

a. The Orthofix Cervical Stim Limited Guarantee Program provides that a refund will be processed if X-rays taken on or after 180 days (i.e., 6 months) of use confirm the absence of fusion.

b. The Orthofix Physio-Stim Limited Guarantee Programs provide that the refund will be processed if X-rays confirm the absence of progression of bony union at 120 days (i.e., 4 months)) or the absence of complete bony union at 180 days.

c. The Orthofix Spinal-Stim Limited Guarantee Program provides for a refund if fusion does not occur after 270 days (i.e., 9 months). During at least 2003-4, the refund was available at 6 months.

d. In its SEC 10-K filing for the year ending 2003, Orthofix stated that "[o]ver the multi-year history of these programs, we have received few claims for reimbursement for which we carry a nominal financial reserve."

75. During at least 2004, defendant Smith & Nephew offered a "Limited Reimbursement Program" for its Exogen device under which a refund would be processed if X-rays "demonstrate[d] no progression to healing during the 180-day treatment period." This program appears to have been discontinued.

RELATOR'S DISCOVERY OF FRAUDULENT SCHEME

76. As set forth above, the relator is the part owner and operator of a company that provides DME billing and related services to health care providers.

77. In or about April 2003, a physician client ("the physician client") told the relator that he was looking to diversify and expand his practice by, amongst other things, becoming a supplier of the medical equipment that he was prescribing for his patients. That equipment included osteogenesis stimulators. The relator undertook to research their purchase price and reimbursement.

78. In researching the clinical indications, the relator learned that the spinal problems treated with devices reimbursed under E0748 are common in the over-65

Medicare population and that Medicare fee schedule payments are extremely generous.

79. He also ascertained that a CMN is required for reimbursement under E0747 and E0748. When he reported his findings to the physician client, the physician client told the relator that he had "never seen" a CMN for an osteogenesis stimulator, despite the fact that he had prescribed more than 100 of them.

80. In or about June 2003, a hospital client of the relator forwarded to the relator a CMN for an E0747 device that had been prescribed for a Medicare patient. The hospital client said that the sales representative of the manufacturer told her that osteogenesis stimulators are always billed as a purchase. The relator noted, however, that the number in the section marked: "est. length of need (# of months)" on the CMN was "9." The relator told the hospital client that the device could not be billed as a purchase and would have to be billed as a rental. The relator's office completed Section C of the CMN indicating that the item would be billed at the Medicare fee schedule amount of $297.93 per month and billed the device accordingly using the RR modifier on the 1500 Form. The patient used the device for 3 months. Medicare allowed the total amount claimed, $893.79, for three months' rental. With the deduction of co-insurance, the total paid by Medicare for the device was $715.02.

81. In or about August 2004, an EBI representative answering a consumer enquiry said that its osteogenesis stimulators were not available for rental, only purchase, at a cost of $3,600. He said that they would achieve bone healing in 3-6 months although they had a longer "shelf life" of 9 months.

82. In or about August 2004, a DJO representative answering a consumer enquiry said that its osteogenesis stimulators were available for purchase only, at $3,700. The representative said in substance that the FDA had designated the devices for single patient use only and that the government "would not allow us to sterilize or resell the product."

83. In or about August 2004, a second EBI representative answering a consumer enquiry said that the devices could be purchased for around $3,000-$4,000. The representative said that in cases of need EBI would take used devices back, refurbish them and give them to indigents. The representative said that the company would write off the unpaid balance of the purchase price that Medicare doesn't cover, i.e., the 20% co-payment.

84. In or about January 2005, an equipment supplier client of the relator forwarded to him a completed prescription and a CMN for an E0748 device for a Medicare patient. The prescription provided four options next to a section for "duration of need:" 6 months, 12 months, 24 months and Lifetime. The 12 months option had been checked. In Section B of the CMN, in the box marked "est. length of need

(# of months)," the code "99" had been entered, indicating lifetime. The supplier client said that the "12 months" option on the prescription had been checked because a bone growth stimulator only works for twelve months.[9] The supplier client said that in practice the doctor would monitor the patient's fusion and might decide three months into the treatment that the bone has fused and the use of the device could be discontinued. The client said that the doctor had probably written "99" in the "est. length of need" box on the CMN because "in his mind he knows it's a purchase only item and it's not a rental item." The client acknowledged that there was a Medicare rental code and said: "but this is just what the manufacturers are telling me … they do these all the time … they tell me that they don't rent them they purchase them … one person gets them and that's it."

85. In or about February 2005 the sales representative at Orthofix from whom the client had acquired the device ("the Orthofix rep") said that osteogenesis stimulators were only made by three companies and that they were all "purchase only" items. The Orthofix rep said that "nobody honors [the rental code] at all." The Orthofix rep said that the devices are used until the doctor determines that fusion has occurred and then "you can chuck it." The Orthofix rep said that the units "lock up after 12 months"[10] and have no secondary use.

[9] This is incorrect. E0747 and E0748 devices automatically deactivate after 9 months.

[10] Id.

86. In or about March 2005 a Smith & Nephew representative told the relator that its osteogenesis stimulators were always billed as a purchase. The Smith & Nephew representative said that the company tells patients they can dispose of the device when they no longer need it. He said the company used to reclaim the devices to track healing times but no longer does that. He said the period of patient use varies but usually is about three months.

87. In or about May 2005, a spine surgeon from Denver, Colorado, told the relator that EBI provides him with free osteogenesis stimulators for his indigent patients, provided that they get his insurance business. He told the relator, in substance, that "the company gives me all the product that I need."

88. The surgeon also told the relator that he had never signed a Certificate of Medical Necessity for an osteogenesis stimulator.

89. Between March 2007 and December 2008, the relator, as a representative of a company purporting to supply medical devices and provide billing services to physicians ("the Company"), had numerous conversations with representatives of Orthofix, DJO and EBI, with a view to purchasing osteogenesis stimulators and other medical devices and supplies from them.

90. In or about March 2007, the relator met with an Orthofix Regional Vice-President ("the Orthofix VP") and two Orthofix sales representatives. The Orthofix VP said

that their osteogenesis stimulators were single patient use and not available for rental. He said that Orthofix had tried renting them in South Carolina where Medicaid only pays for rental, but it wasn't economical. The units had to be serviced and the length of use had to be documented, amongst other things. He said that Orthofix doesn't rent them and won't supply them to anyone who wants to rent. He said that a former Orthofix employee had figured out how to by-pass the shut-off feature. He set up his own business and began picking up units from patients and reprogramming them. Orthofix changed the technology so that he was no longer able to do that. Referring to the devices that were routinely sold on E-Bay, he noted that "some of them work." He said that a company called R&S Medical had tried to have the FDA change the classification for the devices so that they could manufacture and market their own devices without having to file a Premarket Approval Application. He said this would have messed up the reimbursement model because everyone would be making them and the prices would fall. During a conversation with the relator in or about May 2007, an Orthofix executive told the relator that the devices cost about $50-$100 to manufacture.

91. In or about April 2007, the relator met with a DJO Vice President ("the DJO VP") who told him that osteogenesis stimulators were single use devices and could not be rented. When the relator asked him for a document from Medicare supporting that he replied, in substance, that "everyone just knows it." He told the relator that a company tried to have the FDA reclassify osteogenesis stimulators from

"Class III" into "Class II," which would have caused the market to be opened up to rentals. He said the manufacturers got together and were able to block the reclassification.

92. The relator met with the DJO VP and a DJO Regional Director in or about May 2007. The DJO VP said that they always put "lifetime" or 9 months on the "est. length of need" field in the CMNs for the devices. He also said the devices were used on average for about 4-5 months. He again said that the devices were single use and that they were always billed as a purchase. He said there are four manufacturers of the devices and that none of the manufacturers ever rents the devices. He said that there was no rental code. When the relator pointed out the rental code, he said in substance that it "doesn't work." When the relator asked about compliance with Supplier Standard No. 5, the DJO Regional Director said that they don't give the Supplier Standard No. 5 option to the patient. The DJO VP said that the Supplier Standards were general regulations and, in substance, "don't apply to us."

93. The relator met with a second DJO Regional Director ("the DJO Regional Director") in or about November 2007 to discuss the potential purchase of DJO osteogenesis stimulators by the Company. He told the relator that the Company would not be permitted to rent the devices and that if the Company did so DJO would stop selling to them.

94. In or about February 2008 the relator spoke with a second DJO Vice President, who said that none of the four manufacturers offered osteogenesis stimulators for rent because they were single use devices. She said that if the Company were to rent the devices, they would not make any money. She said that a worker's compensation group in New York wanted to rent the devices, and that the four companies got together and told the group that they would not supply it if they turned it into a rental item. She said that DJO wanted its money up front, and that the Company would be best served to do so as well.

95. In or about November 2008 the relator met with the DJO Regional Director, who told him that a company in Austin was caught renting the devices and DJO stopped selling to them. He said that even though Medicare would pay for it as a rental, in substance, "you just can't afford to do that because you will lose money every time."

96. In February 2007, the relator met with an EBI general manager for bone growth stimulators who handed him a business card headed "Biomet." In or about February 2008, the relator had a follow up conversation with an EBI executive about the potential for the Company to purchase osteogenesis stimulators from EBI and about the related reimbursement issues. The EBI executive told the relator that the devices were Class III single use devices and could not be rented. She acknowledged however that the FDA does not make billing policy or regulate reimbursement. She said that if the Company were to rent the devices EBI would

cancel their contract. She said that none of the four manufacturers gave the patient the option to rent the devices and that Supplier Standard No. 5 does not apply to osteogenesis stimulators. When the relator said that he believed Supplier Standard No. 5 applied to all DME, she referred him to a reimbursement consultant ("the EBI Consultant").

97. The relator had various conversations with the EBI Consultant between March 2008 and December 2008. During those conversations, the relator explained that the EBI executive had told him that osteogenesis stimulators were purchase only items, even though Medicare rules required that the patient be offered an option to rent. The EBI Consultant agreed with his explanation of Medicare rules and said she would get back to him. During subsequent conversations with the relator, she told him that it was suggested she not open that can of worms. She said, in substance, "if it's not broke, don't fix it." She said that since no-one has had a problem, there was no need to mess with it. She said that she had been cautioned not to bring this to the attention of her contacts in Medicare and that the companies were hiding it. She said that everyone was going along with it and at some point Medicare would probably turn the device into a rental item but they would cross that bridge when they came to it.

98. In or about February 2008 an EBI executive sent the relator copies of a standard "Service Agreement," headed "Biomet" and a standard form headed "Information On Insurance Coverage and Balance Due," headed "Biomet," both of which EBI

provided to patients when they received an osteogenesis stimulator. The form stated that Medicare patients "can expect an approximate balance due of $720 (average Medicare allowable ~$3,000 x 20%)." The form did not state that the patient had an option to rent the device. The EBI executive also sent the relator forms entitled "Certificate of Medical Necessity/Prescription" for an E0747 device and an E0748 device each headed "Biomet Osteobiologics." All of these documents had a footer stating: "Copyright 2007, Biomet." This footer also stated "Biomet" with the address of EBI, 100 Interpace Parkway, Parsippany, New Jersey 07054.

99. In or about April 2006, a client of the relator told him that defendant Smith & Nephew has a "personal courtesy unit program" whereby doctors are given free osteogenesis stimulators for their indigent patients. The client said that the program is designed to get the doctors' business on billable units.

100. In or about October 2005, a client of the relator told him that Smith & Nephew markets its osteogenesis stimulators through a network of independent distributors who are paid a percentage of the billings (including Medicare and Medicaid billings) that they generate. The client said that the distributors collect the prescription from the doctor and send it to Smith & Nephew, which bills Medicare directly for the device. The distributors deliver the item to the beneficiary. This program was discontinued in or around the end of 2007 and the commission sales agents became company employees. This came at a time when

Smith & Nephew entered into a Deferred Prosecution Agreement with the federal government as part of the settlement of charges that between 2002 and 2006, Smith & Nephew, along with four other medical device manufacturers (including Defendant Biomet, Inc.), engaged in a criminal conspiracy to violate the anti-kickback laws by paying physicians for the purpose of exclusively using their products, specifically hip and knee implants.[11]

101. In or about March 2007, the Orthofix VP referred to in paragraph 90 above told the relator that Orthofix paid commissions to independent sales agents such as the Company for referrals of osteogenesis stimulator business to Orthofix, including osteogenesis stimulators billed to Medicare and Medicaid. He identified a company called DME Solutions as one such independent agent who received commissions for placing Orthofix osteogenesis stimulators with physicians. He stated that the commissions consisted of either a percentage of the reimbursement or a flat fee and were paid only if Orthofix was reimbursed for the product. In discussions occurring between March and May 2007, the Orthofix executive offered to pay the Company a commission for the referral of osteogenesis stimulator business from doctors affiliated with the Company.

102. During the discussion in or about March 2007, the Orthofix VP told the relator that Orthofix had a "buy ten, get one free" program for third party

[11] Press Release, U.S. Attorney for the District of New Jersey, September 27, 2007, http://www.justice.gov/usao/nj/press/files/pdffiles/hips0927.rel.pdf (last visited April 4, 2010)

suppliers who purchased a high volume of product from Orthofix. He stated that Orthofix did not have a "volume discount" program as such, but that it did have a program whereby it provided a free unit, which Orthofix termed a "compassionate care" unit, for every ten purchased. While this free unit was ostensibly for doctors to give away to their indigent patients, the Orthofix VP told the relator that the unit could be billed to Medicare rather than given away free. Since the unit was free, no discount would be reflected on invoices sent by Orthofix to the buyer.

103. Orthofix and the Company subsequently executed a contract for the purchase of osteogenesis stimulators from Orthofix on the terms set forth in the immediately preceding paragraph. The Orthofix VP indicated that Orthofix enters into similar agreements with other suppliers.

104. In or about March 2007, the relator met with the DJO VP referred to in paragraph 91 above to discuss the potential for the Company to purchase DJO osteogenesis stimulators. The DJO VP explained that the Company could either buy the units from DJO and then bill for them directly, or DJO could bill for the units and pay the Company a percentage of the reimbursement for referral of the business to doctors affiliated with the Company. Both arrangements included units that would be billed to Medicare and Medicaid. The relator had various discussions on this and other matters relating to the supply and billing of

osteogenesis stimulators with the DJO VP and two other DJO executives between March 2007 and November 2008.

105. During these discussions, a DJO executive told the relator that DJO routinely gave free osteogenesis stimulators to doctors in order to encourage the doctors to send their paying business, including Medicare and Medicaid, to DJO. The DJO executive stated that DJO would provide free units to doctors associated with the Company.

106. In or about December 2007 a DJO executive sent to the relator a draft standard form "Sales Agreement" for the sale of DJO osteogenesis stimulators to the Company and a draft standard form "Referral Agreement" for the referral of business to DJO from physicians affiliated with the Company.

107. The standard form "Sales Agreement" provided *inter alia* for the buyer to receive volume discounts on the purchase of DJO osteogenesis stimulators as follows:

	5-10 units	10+ units	20+ units
E0747	$2,000 each	$1,900 each	$1,800 each
E0748	$2,600 each	$2,500 each	$2,400 each

108. The "Sales Agreement" also required the buyer to ensure its compliance with federal and state fraud and abuse statutes and regulations. However, during discussions with the relator in or about January 2008 and in or about November

2008 the DJO Regional Director referred to in paragraph 93 above stated that the volume discounts would not be reflected on the invoices sent by DJO to the Company so that they would not have to be disclosed to Medicare.

109. The Sales Agreement was executed by DJO and the Company in or about January 2008. The DJO Regional Director told the relator that DJO gave similar volume discounts to other suppliers, including Ortho RX and Pinnacle Orthopedics. In fact, the draft Sales Agreement sent to the relator included the name "Pinnacle Orthopedics" as the buyer, apparently due to an oversight by DJO.

110. The DJO standard form "Referral Agreement" referred to in paragraph 106 above provided for DJO to contract with entities having established relationships with physicians for the referral of orders for osteogenesis stimulators from physicians who were not currently customers of DJO. The Referral Agreement provided *inter alia* for DJO to pay the entity (described as "Contractor") ten percent (10%) of the allowed amount for each referral that resulted in a completed order that DJO invoiced at $2,000 or more. Under the Referral Agreement, DJO was responsible for preparing the paperwork needed to process the order. While the Referral Agreement required the Contractor to warrant that it had no financial relationship with any physicians or other health care providers who were in a position to refer patients to DJO for furnishing DJO items or services, DJO executives knew that the Company apparently had such

relationships. The Referral Agreement was executed by DJO and the Company in or about January 2008.

111. During the discussions between the relator and the DJO Regional Manager referred to in paragraph 93 above, the DJO Regional Director stated that the Referral Agreement applied to units billed to Medicare and Medicaid. He explained that DJO has a lot of sales agents participating in Referral Agreements, some of whom were receiving 20% of the reimbursement for both providing the referrals and preparing the paperwork necessary to process the orders. He stated that DJO's growth in sales for osteogenesis stimulators was due largely to these sales agents.

112. In or about February 2008 an EBI executive sent a draft standard form contract for the sale of EBI osteogenesis stimulators to the relator. In an email forwarding this contract to the relator, the subject line read: "Draft Biomet Agreement." This contract provided *inter alia* for the buyer to receive a volume discount on the purchase of eleven or more EBI osteogenesis stimulators per month, including units that would be billed to Medicare and Medicaid. The contract stated a price of $2,375 per unit for one to ten units per month and a price of $2,275 per unit for more than eleven units per month. The contract also stated that the buyer would pay $2,375 for each unit at the time of purchase and that EBI would pay the buyer a rebate appropriate to the volume discount on "reconciliation dates," which would occur every six months. The contract also

stipulated an "Ordering Process," the effect of which was that no invoices were generated by EBI for the units. Instead, EBI generated a 1500 Form for each unit to be billed by the buyer, and the buyer paid EBI $2,375 within 30 days of receiving the 1500 Form. The effect of this rebate procedure and "Ordering Process" was that EBI would generate no invoices showing the volume discount received by the buyer. The Company and EBI executed this contract in or about February 2008.

FALSE CLAIMS ACT VIOLATIONS

113. The defendants present and cause to be presented false and fraudulent claims for payment to the government for devices that are not medically necessary and reasonable within 42 U.S.C. 1395y(a)(1)(A) for the period of time represented in the claim. When submitting 1500 Forms to the government, the defendants make and cause to be made express false certifications that payment for the items on a purchase basis is justified by medical need, knowing that no such justification exists. In fact, the defendants know that the duration of medical need is rarely in excess of six months and indeed cannot be any period of time in excess of nine months, and could be as little as two months, and thus cannot support a claim for payment on a purchase basis.

114. In furtherance of their fraudulent scheme, the defendants cause physicians and/or their employees to include a number or code in Section B of the CMN in

the section marked: "est. length of need (# of months)" that is inconsistent with the medical needs of the patient. Defendants mislead physicians, their employees, other clinicians and/or suppliers by advising them to include the code "99" in Section B of the CMN (indicating that the patient will need the device for life), or to otherwise include a number of months that is inconsistent with the medical needs of the patient and/or exceeds the useful life of the device itself.

115. Alternatively or in addition to the allegations in paragraph 114 above, on information and belief based on paragraphs 79 and 88 above, and details of which are exclusively within the defendants' possession, the defendants falsify CMNs for osteogenesis stimulators by illegally completing Sections B and/or D of the CMNs, and including information in Section B of the CMN that is inconsistent with the medical needs of the patient. On information and belief, these defendants include false information on CMNs in one or more of the following ways:

a. Entering the code "99" in Section B of the CMN in the section marked: "est. length of need (# of months)" indicating that the patient will need the device for life or otherwise including a number of months that is inconsistent with the medical needs of the patient and exceeds the useful life of the device itself;

b. Signing and dating Section D on behalf of or in place of the physician attesting *inter alia* that the medical necessity information in Section B is true, accurate and complete.

116. Defendants submit the falsified CMNs referred to in paragraphs 114 and 115 above to Medicare with their false claims for payment for osteogenesis stimulators in order to get Medicare to pay the claims on a purchase basis.

117. In furtherance of their fraudulent scheme, commencing on or about December 11, 2000, the defendants routinely violate the Supplier Standards. The defendants control the market for osteogenesis stimulators and do not offer them as rental items. Therefore, they cannot have advised beneficiaries that they may either rent or purchase them as required by Supplier Standard No. 5, 42 C.F.R. 424.57(c) (5), because no such option exists.

118. Compliance with the Supplier Standards is a precondition for payment by Medicare and a precondition for eligibility in the Medicare program. In order to receive payment by Medicare, the defendants certify in their Medicare Enrollment Applications, which are renewed every three years, as follows: "I agree to abide by the Medicare laws, regulations and program instructions that apply to this supplier ... I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions … and on the supplier's compliance with all

applicable conditions of participation by Medicare." The Medicare Enrollment Application includes an abbreviated version of the Supplier Standards, cites 42 C.F.R. §424.57(c) and states on its cover page that "every applicant must meet and maintain these enrollment standards." As a result of the defendants' violations of the Supplier Standards, the defendants' certifications in their Medicare Enrollment Applications are false, and all claims made to Medicare by the defendants for osteogenesis stimulators are false. When the defendants made these certifications they knew that they had been,[12] were, and would continue to be in violation of the Supplier Standards. Had Medicare known of the defendants' violations of the Supplier Standards and the false certifications of compliance therewith, it would not have permitted enrolment in the Medicare program and would not have paid for the items and would have revoked the defendants' billing privileges pursuant to 42 C.F.R. 424.57(d).

119. As a result of the conduct alleged in the immediately preceding paragraphs 113-118 and in light of the allegation in paragraph 48 above that osteogenesis stimulators should always be billed as rental items and never billed as purchase items, all claims to Medicare, Medicaid and other government health plans for osteogenesis stimulators as purchase items are false. This includes claims submitted by the defendants and claims by third party suppliers that the defendants caused to be submitted as a result of their conduct as alleged herein. A schedule of claims for E0747 and E0748 devices submitted to Medicare by the

[12] With respect to the initial Medicare Enrollment Applications submitted by the defendants in or about December 2000, the defendants knew that they were and would continue to be in violation of the Supplier Standards.

defendants[13] for the period 1993 through 2006 is attached hereto in Exhibit A, showing the HCPCS code, supplier name and number, description of item billed, DMERC Region in which billed, year submitted or paid, the amount submitted and allowed, the amount the provider and beneficiary were paid, the number of services allowed and the number denied, and the modifier used in submitting the claim, indicating that the "NU" modifier was submitted in every case. A schedule of claims submitted to Medicare by Smith & Nephew during a six month period in 2002 is attached hereto in Exhibit B, showing the date of the claim, the DMERC Region, the beneficiary's city, state and zip code, the supplier number and name, the physician's UPIN (Unique Physician Identification Number) and the amount Medicare paid, indicating that the device was reimbursed on a purchase basis in every case. A sample of individual claims submitted by the defendants[14] during 2001 and 2002 is attached hereto in Exhibit C, showing the date of the claim, the DMERC Region, the beneficiary's city, state and zip code, the supplier number and name, the physician's UPIN and the amount Medicare paid, indicating that the device was reimbursed on a purchase basis in every case.

120. As further set forth in paragraphs 121-123 below, from at least 2005 and continuing to the date hereof, the defendants also furnish osteogenesis stimulators

[13] The billing entities identified in Exhibit A are American Medical Electronics (which was acquired by Orthofix in 1995), Bioelectron, Inc., DJ Orthopedics LLP, EBI, LP, Exogen Inc. (which was acquired by Smith & Nephew in 1999), Orthofix, Inc., and Orthologic Corp.

[14] Other than DJO. There is no data for this period for DJO, which did not manufacture osteogenesis stimulators until 2003.

in violation of the anti-kickback act. These allegations do not apply to defendant Orthologic.

121. Compliance with the anti-kickback act is a precondition for payment by Medicare. In order to receive payment by Medicare, the defendants certify in their Medicare Enrollment Applications, which are renewed every three years, as follows: "I agree to abide by the Medicare laws, regulations and program instructions that apply to this supplier ... I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law,) and on the supplier's compliance with all applicable conditions of participation by Medicare." When the defendants made these certifications they knew that they had been, were, and would continue to be in violation of the anti-kickback act. As a result of this and the defendants' violations of the anti-kickback act, the defendants' certifications in their Medicare Enrollment Applications are false, and all claims to Medicare for osteogenesis stimulators arising from such violations are false.

122. In addition or alternatively, since defendants violate the anti-kickback act, and since Medicare and Medicaid do not cover items or services that are provided because of illegal inducements, all claims for payment for those items and services are false.

123. The defendants' violations of the anti-kickback act include the following:

a. Providing doctors with free devices.

i. As set forth in paragraphs 83, 87, 99, 102, 103, and 105 above, the defendants routinely provide doctors with free osteogenesis stimulators in exchange for their Medicare, Medicaid and private payor business.

ii. The defendants violate the anti-kickback act by offering and/or providing to doctors something of value (i.e., free units) as an inducement to generate business for themselves payable by Medicare or Medicaid. All claims for payment submitted by the defendants or third party suppliers for osteogenesis stimulators prescribed by physicians who received free units from the defendants are false. Records identifying those prescribing physicians and tracking orders from those physicians to claims made by the defendants to Medicare and Medicaid are solely within the possession of the defendants. Relator alleges on information and belief that such claims were made and that the identifying records, orders and claims will be obtained during discovery, based on paragraphs 83, 87, 99, 102, 103, and 105 above indicating that free units are routinely and frequently given

to physicians by the defendants, particularly those physicians who prescribe a high volume of osteogenesis stimulators for Medicare and Medicaid patients.

b. Using independent sales agents.

i. As set forth in paragraphs 100, 101, 104, 110, and 111 above, defendants Smith & Nephew, Orthofix and DJO routinely pay commissions to independent sales agents, including commissions based on a percentage of the Medicare, Medicaid and other billings that the agents generate.

ii. Defendants Smith & Nephew, Orthofix and DJO violate the anti-kickback act by offering and/or providing to independent sales agents something of value (i.e., compensation) as an inducement to generate business for themselves payable by Medicare or Medicaid.

iii. All claims submitted to Medicare and Medicaid for osteogenesis stimulators for which an independent sales agent received a commission from these defendants are false. Records tracking claims made by these defendants to Medicare and Medicaid for units for which a referral fee or commission was paid to

independent sales agents are solely within the possession of the defendants. Relator alleges on information and belief that such claims were made and that the identifying records and claims will be obtained during discovery, based on paragraphs 100, 101, 104, 110, and 111 above, indicating that executives from DJO and Orthofix told the relator that they entered into commission sales agreements similar to the one entered into by the Company with other entities (and in fact, in the case of DJO, that such agreements were responsible for an increase in sales volume), and that a client of the relator told him that prior to the end of 2007 Smith & Nephew marketed its osteogenesis stimulators through a network of independent commission sales agents.

c. Giving third party suppliers volume discounts.

i. As set forth in paragraphs 102, 103, 106, 107, 108, 109, and 112 above, defendants EBI, Orthofix and DJO give third party suppliers volume discounts on the purchase of osteogenesis stimulators, knowing that those suppliers will seek reimbursement from Medicare, Medicaid and other government health plans for those units. These volume discounts are not reflected on invoices sent to the third party suppliers by EBI, Orthofix and DJO.

ii. This violates the anti-kickback act discount "safe harbor" regulations set forth in 42 C.F.R. § 1001.952(h)(2)(iii)(B), requiring a seller providing a discount to a buyer of items or services paid for by Medicare or Medicaid to "fully and accurately report such discount on the invoice, coupon or statement submitted to the buyer … and refrain from doing anything that would impede the buyer from meeting its obligations" to disclose the discount to HHS upon request under 42 C.F.R. §1001.952(h)(1)(iii)(B). Therefore, discounts given to third party suppliers pursuant to agreements with EBI, Orthofix and DJO on terms similar to those set forth in paragraphs 102, 103, 106, 107, 108, 109, and 112 above do not qualify for the "safe harbor" exception and violate the anti-kickback act.

iii. All claims for osteogenesis stimulators billed to Medicare and Medicaid by suppliers who received discounts from EBI, Orthofix and DJO pursuant to such agreements are false. Records identifying these suppliers are solely within the possession of the defendants and the suppliers. Relator alleges on information and belief that those suppliers made claims to Medicare and that the identifying records and claims will be obtained during discovery, based on paragraphs 102, 103, 106, 107, 108, 109, and 112 above, indicating that executives from DJO and Orthofix told the relator

that they entered into volume discount agreements similar to the one executed by the Company with other suppliers, and that contracts containing volume discounts entered into by DJO and EBI with the Company were standard form agreements and not exclusive to the Company.

DAMAGES

124. Between 1998 and 2008 Medicare paid approximately $400 million for osteogenesis stimulators.

125. Relator contends that three times the full amount paid by Medicare and other government health programs for osteogenesis stimulators is recoverable from the defendants, for the following reasons:

a. The defendants' violations of the FCA, the criminal law and Medicare regulations are multiple and egregious, including: falsification of CMNs, a criminal offense under 18 U.S.C. § 1035; express false certifications of medical necessity in 1500 Forms, also a violation of 18 U.S.C. § 1035; and inducing physicians and their employees to include false information on CMNs via misrepresentations. Medicare and Medicaid do not cover items and services procured by illegal acts and inducements that were

designed to deceive the government into making payments that otherwise would have been withheld.

b. The defendants violated the Supplier Standards, 42 C.F.R. 424.57 (c) (1) and (5). Compliance with the Supplier Standards is a precondition for payment by Medicare, and all claims submitted from in or about December 2000 to the present are false. Further, 42 C.F.R. 424.57(d) states that "CMS will revoke a supplier's billing privileges if it is found not to meet the standards in paragraphs (b) and (c) of this section." Therefore, had CMS been aware of these violations, it would have revoked the defendants' billing privileges and the defendants would have received no payment for the devices.

[continued on next page]

CAUSES OF ACTION

FIRST CAUSE OF ACTION
(Federal False Claims Act
31 U.S.C. § 3729(a)(1))

126. Plaintiff/relator repeats and realleges each and every allegation contained in paragraphs 1 through 125 above as though fully set forth herein again at length.

127. This is a claim for penalties and treble damages under the Federal False Claims Act.

128. By virtue of the acts described above, Defendants, for the purpose of defrauding the Government, knowingly presented and/or caused to be presented false or fraudulent claims for payment or approval under the Medicare, Medicaid and other Government health programs to officers, employees or agents of the United States Government, within the meaning of 31 U.S.C. § 3729(a)(1).

129. As a result, federal monies were lost through payments made in respect of the claims and other costs were sustained by the Government.

130. Therefore, the Federal Government has been damaged in an amount to be proven at trial.

131. Additionally, the Federal Government is entitled to the maximum penalty of $11,000 for each and every false and fraudulent claim made and caused to be

made by Defendants and arising from their fraudulent conduct as described herein.

SECOND CAUSE OF ACTION
(Federal False Claims Act
31 U.S.C. § 3729(a)(2))

132. Plaintiff/relator repeats and realleges each and every allegation contained in paragraphs 1 through 125 above as though fully set forth herein again at length.

133. This is a claim for penalties and treble damages under the Federal False Claims Act.

134. By virtue of the acts described above, the Defendants, for the purpose of defrauding the Government, knowingly made, used and/or caused to be made or used, false or fraudulent records or statements to get false and fraudulent claims paid or approved under Medicare, Medicaid and other Government health programs, within the meaning of 31 U.S.C. § 3729(a)(2).

135. As a result, federal monies were lost through payments made in respect of the claims and other costs were sustained by the Government.

136. Therefore, the Federal Government has been damaged in an amount to be proven at trial.

137. Additionally, the Federal Government is entitled to the maximum penalty of $11,000 for each and every false and fraudulent claim paid or approved arising from the Defendants' fraudulent conduct as described herein.

THIRD CAUSE OF ACTION
(Federal False Claims Act
31 U.S.C. § 3729(a)(1)(A))

138. Plaintiff/relator repeats and realleges each and every allegation contained in paragraphs 1 through 125 above as though fully set forth herein again at length.

139. This is a claim for penalties and treble damages under the Federal False Claims Act.

140. By virtue of the acts described above, Defendants, for the purpose of defrauding the Government, knowingly presented and/or caused to be presented false or fraudulent claims for payment or approval under the Medicare, Medicaid and other Government health programs, within the meaning of 31 U.S.C. § 3729(a)(1)(A).

141. As a result, federal monies were lost through payments made in respect of the claims and other costs were sustained by the Government.

142. Therefore, the Federal Government has been damaged in an amount to be proven at trial.

143. Additionally, the Federal Government is entitled to the maximum penalty of $11,000 for each and every false and fraudulent claim made and caused to be made by Defendants and arising from their fraudulent conduct as described herein.

FOURTH CAUSE OF ACTION
(Federal False Claims Act
31 U.S.C. § 3729(a)(1)(B))

144. Plaintiff/relator repeats and realleges each and every allegation contained in paragraphs 1 through 125 above as though fully set forth herein again at length.

145. This is a claim for penalties and treble damages under the Federal False Claims Act.

146. By virtue of the acts described above, the Defendants, for the purpose of defrauding the Government, knowingly made, used and/or caused to be made or used, false records or statements material to a false or fraudulent claims paid or approved under Medicare, Medicaid and other Government health programs, within the meaning of 31 U.S.C. § 3729(a)(1)(B).

147. As a result, federal monies were lost through payments made in respect of the claims and other costs were sustained by the Government.

148. Therefore, the Federal Government has been damaged in an amount to be proven at trial.

149. Additionally, the Federal Government is entitled to the maximum penalty of $11,000 for each and every false and fraudulent claim paid or approved arising from the Defendants' fraudulent conduct as described herein.

FIFTH CAUSE OF ACTION
(California False Claims Act
Cal. Gov't Code § 12651(a)(1))

150. Plaintiff/relator repeats and realleges each and every allegation contained in paragraphs 1 through 125 above as though fully set forth herein.

151. This is a claim for penalties and treble damages under the California False Claims Act.

152. By virtue of the acts described above, Defendants, for the purpose of defrauding the California State Government, knowingly presented and/or caused to be presented false claims for payment or approval under Medicaid and other California State funded programs to officers or employees of the state within the meaning of Cal. Gov't Code § 12651(a)(1).

153. As a result, California State monies were lost through payments made in respect of the claims and other costs were sustained by the California State Government.

154. Therefore, the California State Government has been damaged in an amount to be proven at trial.

155. Additionally, the California State Government is entitled to the maximum penalty of $10,000 for each and every false claim presented and caused to be presented by Defendants and arising from their fraudulent conduct as described herein.

SIXTH CAUSE OF ACTION
(California False Claims Act
Cal. Gov't Code § 12651(a)(2))

156. Plaintiff/relator repeats and realleges each and every allegation contained in paragraphs 1 through 125 above as though fully set forth herein.

157. This is a claim for penalties and treble damages under the California False Claims Act.

158. By virtue of the acts described above, Defendants, for the purpose of defrauding the California State Government, knowingly made, used, and/or caused to be made or used, false records or statements to get false claims paid or

approved under Medicaid and other California State funded programs within the meaning of Cal. Gov't Code § 12651(a)(2).

159. As a result, California State monies were lost through payments made in respect of the claims and other costs were sustained by the California State Government.

160. Therefore, the California State Government has been damaged in an amount to be proven at trial.

161. Additionally, the California State Government is entitled to the maximum penalty of $10,000 for each and every false claim paid or approved arising from the Defendants' fraudulent conduct as described herein.

SEVENTH CAUSE OF ACTION
(Delaware False Claims and Reporting Act
6 Del. C. § 1201(a)(1))

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162. Plaintiff/relator repeats and realleges each and every allegation contained in paragraphs 1 through 125 above as though fully set forth herein.

163. This is a claim for penalties and treble damages under the Delaware False Claims and Reporting Act.

164. By virtue of the acts described above, Defendants, for the purpose of defrauding the Delaware State Government, knowingly presented and/or caused to be presented, directly or indirectly, false or fraudulent claims for payment or approval under Medicaid and other Delaware State funded programs to officers or employees of the state within the meaning of 6 Del. C. § 1201(a)(1).

165. As a result, Delaware State monies were lost through payments made in respect of the claims and other costs were sustained by the Delaware State Government.

166. Therefore, the Delaware State Government has been damaged in an amount to be proven at trial.

167. Additionally, the Delaware State Government is entitled to the maximum penalty of $11,000 for each and every false and fraudulent claim presented and caused to be presented by Defendants and arising from their fraudulent conduct as described herein.

EIGHTH CAUSE OF ACTION
(Delaware False Claims and Reporting Act
6 Del. C. § 1201(a)(2))

168. Plaintiff/relator repeats and realleges each and every allegation contained in paragraphs 1 through 125 above as though fully set forth herein.

169. This is a claim for penalties and treble damages under the Delaware False Claims and Reporting Act.

170. By virtue of the acts described above, Defendants, for the purpose of defrauding the Delaware State Government, knowingly made, used, and/or caused to be made or used, directly or indirectly, false records or statements to get false or fraudulent claims paid or approved under Medicaid and other Delaware State funded programs within the meaning of 6 Del. C. § 1201(a)(2).

171. As a result, Delaware State monies were lost through payments made in respect of the claims and other costs were sustained by the Delaware State Government.

172. Therefore, the Delaware State Government has been damaged in an amount to be proven at trial.

173. Additionally, the Delaware State Government is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim paid or approved arising from the Defendants' fraudulent conduct as described herein.

NINTH CAUSE OF ACTION
(District of Columbia Procurement Reform Amendment Act
D.C. Code § 2-308.14(a)(1))

174. Plaintiff/relator repeats and realleges each and every allegation contained in paragraphs 1 through 125 above as though fully set forth herein.

175. This is a claim for penalties and treble damages under the District of Columbia Procurement Reform Amendment Act.

176. By virtue of the acts described above, Defendants, for the purpose of defrauding the District of Columbia Government, knowingly presented and/or caused to be presented, false claims for payment or approval under Medicaid and other District of Columbia funded programs to officers or employees of the District within the meaning of D.C. Code § 2-308.14(a)(1).

177. As a result, District of Columbia monies were lost through payments made in respect of the claims and other costs were sustained by the District of Columbia Government.

178. Therefore, the District of Columbia Government has been damaged in an amount to be proven at trial.

179. Additionally, the District of Columbia Government is entitled to the maximum penalty of $10,000 for each and every false claim presented and caused

to be presented by Defendants and arising from their fraudulent conduct as described herein.

TENTH CAUSE OF ACTION
(District of Columbia Procurement Reform Amendment Act
D.C. Code § 2-308.14(a)(2))

180. Plaintiff/relator repeats and realleges each and every allegation contained in paragraphs 1 through 125 above as though fully set forth herein.

181. This is a claim for penalties and treble damages under the District of Columbia Procurement Reform Amendment Act.

182. By virtue of the acts described above, Defendants, for the purpose of defrauding the District of Columbia Government, knowingly made, used, and/or caused to be made or used, false records or statements to get false claims paid or approved under Medicaid and other District of Columbia funded programs within the meaning of D.C. Code § 2-308.14(a)(2).

183. As a result, District of Columbia monies were lost through payments made in respect of the claims and other costs were sustained by the District of Columbia Government.

184. Therefore, the District of Columbia Government has been damaged in an amount to be proven at trial.

185. Additionally, the District of Columbia Government is entitled to the maximum penalty of $10,000 for each and every false claim paid or approved arising from the Defendants' fraudulent conduct as described herein.

ELEVENTH CAUSE OF ACTION
(Florida False Claims Act
Fla. Stat. § 68.082(2)(a))

186. Plaintiff/relator repeats and realleges each and every allegation contained in paragraphs 1 through 125 above as though fully set forth herein.

187. This is a claim for penalties and treble damages under the Florida False Claims Act.

188. By virtue of the acts described above, Defendants, for the purpose of defrauding the Florida State Government, knowingly presented and/or caused to be presented false claims for payment or approval under Medicaid and other Florida State funded programs to officers or employees of the state within the meaning of Fla. Stat. § 68.082(2)(a).

189. As a result, Florida State monies were lost through payments made in respect of the claims and other costs were sustained by the Florida State Government.

190. Therefore, the Florida State Government has been damaged in an amount to be proven at trial.

191. Additionally, the Florida State Government is entitled to the maximum penalty of $10,000 for each and every false claim presented and caused to be presented by Defendants and arising from their fraudulent conduct as described herein.

TWELFTH CAUSE OF ACTION
(Florida False Claims Act
Fla. Stat. § 68.082(2)(b))

192. Plaintiff/relator repeats and realleges each and every allegation contained in paragraphs 1 through 125 above as though fully set forth herein.

193. This is a claim for penalties and treble damages under the Florida False Claims Act.

194. By virtue of the acts described above, Defendants, for the purpose of defrauding the Florida State Government, knowingly made, used, and/or caused to be made or used, false records or statements to get false or fraudulent claims paid or approved under Medicaid and other Florida State funded programs within the meaning of Fla. Stat. § 68.082(2)(b).

195. As a result, Florida State monies were lost through payments made in respect of the claims and other costs were sustained by the Florida State Government.

196. Therefore, the Florida State Government has been damaged in an amount to be proven at trial.

197. Additionally, the Florida State Government is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim paid or approved arising from the Defendants' fraudulent conduct as described herein.

THIRTEENTH CAUSE OF ACTION
(Georgia State False Medicaid Claims Act
Ga. Code Ann. § 49-4-168.1(a)(1))

198. Plaintiff/relator repeats and realleges each and every allegation contained in paragraphs 1 through 125 above as though fully set forth herein.

199. This is a claim for penalties and treble damages under the Georgia State False Medicaid Claims Act.

200. By virtue of the acts described above, Defendants, for the purpose of defrauding the Georgia State Government, knowingly presented and/or caused to be presented to the Georgia Medicaid program false or fraudulent claims for payment or approval within the meaning of Ga. Code Ann. § 49-4-168.1(a)(1).

201. As a result, Georgia State monies were lost through payments made in respect of the claims and other costs were sustained by the Georgia State Government.

202. Therefore, the Georgia State Government has been damaged in an amount to be proven at trial.

203. Additionally, the Georgia State Government is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim presented or caused to be presented by Defendants and arising from their fraudulent conduct as described herein.

FOURTEENTH CAUSE OF ACTION
(Georgia State False Medicaid Claims Act
Ga. Code Ann. § 49-4-168.1(a)(2))

204. Plaintiff/relator repeats and realleges each and every allegation contained in paragraphs 1 through 125 above as though fully set forth herein.

205. This is a claim for penalties and treble damages under the Georgia State False Medicaid Claims Act.

206. By virtue of the acts described above, Defendants, for the purpose of defrauding the Georgia State Government, knowingly made, used, and/or caused

to be made or used, false records or statements to get false or fraudulent claims paid or approved by the Georgia Medicaid program within the meaning of Ga. Code Ann. § 49-4-168.1(a)(2).

207. As a result, Georgia State monies were lost through payments made in respect of the claims and other costs were sustained by the Georgia State Government.

208. Therefore, the Georgian State Government has been damaged in an amount to be proven at trial.

209. Additionally, the Georgia State Government is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim paid or approved arising from the Defendants' fraudulent conduct as described herein.

FIFTEENTH CAUSE OF ACTION
(Hawaii False Claims Act
Haw. Rev. Stat. § 661-21(a)(1))

210. Plaintiff/relator repeats and realleges each and every allegation contained in paragraphs 1 through 125 above as though fully set forth herein.

211. This is a claim for penalties and treble damages under the Hawaii False Claims Act.

212. By virtue of the acts described above, Defendants, for the purpose of defrauding the Hawaii State Government, knowingly presented and/or caused to be presented false or fraudulent claims for payment or approval under Medicaid and other Hawaii State funded programs to officers or employees of the state within the meaning of Haw. Rev. Stat. § 661-21)(a)(1).

213. As a result, Hawaii State monies were lost through payments made in respect of the claims and other costs were sustained by the Hawaii State Government.

214. Therefore, the Hawaii State Government has been damaged in an amount to be proven at trial.

215. Additionally, the Hawaii State Government is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim presented and caused to be presented by Defendants and arising from their fraudulent conduct as described herein.

SIXTEENTH CAUSE OF ACTION
(Hawaii False Claims Act
Haw. Rev. Stat. § 661-21(a)(2))

216. Plaintiff/relator repeats and realleges each and every allegation contained in paragraphs 1 through 125 above as though fully set forth herein.

217. This is a claim for penalties and treble damages under the Hawaii False Claims Act.

218. By virtue of the acts described above, Defendants, for the purpose of defrauding the Hawaii State Government, knowingly made, used, and/or caused to be made or used, false records or statements to get false or fraudulent claims paid or approved under Medicaid and other Hawaii State funded programs within the meaning of Haw. Rev. Stat. § 661-21)(a)(2).

219. As a result, Hawaii State monies were lost through payments made in respect of the claims and other costs were sustained by the Hawaii State Government.

220. Therefore, the Hawaii State Government has been damaged in an amount to be proven at trial.

221. Additionally, the Hawaii State Government is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim paid or approved arising from the Defendants' fraudulent conduct as described herein.

SEVENTEENTH CAUSE OF ACTION
(Illinois Whistleblower Reward and Protection Act
740 Ill. Comp. Stat. 175/3(a)(1))

222. Plaintiff/relator repeats and realleges each and every allegation contained in paragraphs 1 through 125 above as though fully set forth herein.

223. This is a claim for penalties and treble damages under the Illinois Whistleblower Reward and Protection Act.

224. By virtue of the acts described above, Defendants, for the purpose of defrauding the Illinois State Government, knowingly presented and/or caused to be presented false or fraudulent claims for payment or approval under Medicaid and other Illinois State funded programs to officers or employees of the state within the meaning of 740 Ill. Comp. Stat. 175/3(a)(1).

225. As a result, Illinois State monies were lost through payments made in respect of the claims and other costs were sustained by the Illinois State Government.

226. Therefore, the Illinois State Government has been damaged in an amount to be proven at trial.

227. Additionally, the Illinois State Government is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim presented and

caused to be presented by Defendants and arising from their fraudulent conduct as described herein.

EIGHTEENTH CAUSE OF ACTION
(Illinois Whistleblower Reward and Protection Act
740 Ill. Comp. Stat. 175/3(a)(2))

228. Plaintiff/relator repeats and realleges each and every allegation contained in paragraphs 1 through 125 above as though fully set forth herein.

229. This is a claim for penalties and treble damages under the Illinois Whistleblower Reward and Protection Act.

230. By virtue of the acts described above, Defendants, for the purpose of defrauding the Illinois State Government, knowingly made, used, and/or caused to be made or used, false records or statements to get false or fraudulent claims paid or approved under Medicaid and other Illinois State funded programs within the meaning of 740 Ill. Comp. Stat. 175/3(a)(2).

231. As a result, Illinois State monies were lost through payments made in respect of the claims and other costs were sustained by the Illinois State Government.

232. Therefore, the Illinois State Government has been damaged in an amount to be proven at trial.

233. Additionally, the Illinois State Government is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim paid or approved arising from the Defendants' fraudulent conduct as described herein.

NINETEENTH CAUSE OF ACTION
(Indiana False Claims and Whistleblower Protection Act
Ind. Code § 5-11-5.5-2(b)(1) and (8))

234. Plaintiff/relator repeats and realleges each and every allegation contained in paragraphs 1 through 125 above as though fully set forth herein.

235. This is a claim for penalties and treble damages under the Indiana False Claims and Whistleblower Protection Act.

236. By virtue of the acts described above, Defendants, for the purpose of defrauding the Indiana State Government, knowingly or intentionally presented and/or caused or induced another to present false claims under Medicaid and other Indiana State funded programs to the state for payment or approval within the meaning of Ind. Code § 5-11-5.5-2(b)(1) and (8).

237. As a result, Indiana State monies were lost through payments made in respect of the claims and other costs were sustained by the Indiana State Government.

238. Therefore, the Indiana State Government has been damaged in an amount to be proven at trial.

239. Additionally, the Indiana State Government is entitled to a civil penalty of at least $5,000 for each and every false or fraudulent claim paid or approved arising from the Defendants' fraudulent conduct as describe herein.

TWENTIETH CAUSE OF ACTION
(Indiana False Claims and Whistleblower Protection Act
Ind. Code § 5-11-5.5-2(b)(2) and (8))

240. Plaintiff/relator repeats and realleges each and every allegation contained in paragraphs 1 through 125 above as though fully set forth herein.

241. This is a claim for penalties and treble damages under the Indiana False Claims and Whistleblower Protection Act.

242. By virtue of the acts described above, Defendants, for the purpose of defrauding the Indiana State Government, knowingly or intentionally made, used, and/or caused or induced another to make or use, false records or statements to obtain payment or approval of a false claim under Medicaid and other Indiana State funded programs within the meaning of Ind. Code § 5-11-5.5-2(b)(2) and (8).

243. As a result, Indiana State monies were lost through payments made in respect of the claims and other costs were sustained by the Indiana State Government.

244. Therefore, the Indiana State Government has been damaged in an amount to be proven at trial.

245. Additionally, the Indiana State Government is entitled to a civil penalty of at least $5,000 for each and every false or fraudulent claim paid or approved arising from the Defendants' fraudulent conduct as describe herein.

TWENTY-FIRST CAUSE OF ACTION
(Louisiana Medical Assistance Programs Integrity Law
La. Rev. Stat. 46:438.3(A))

246. Plaintiff/relator repeats and realleges each and every allegation contained in paragraphs 1 through 125 above as though fully set forth herein.

247. This is a claim for a fine and damages under the Louisiana Medical Assistance Programs Integrity Law.

248. By virtue of the acts described above, Defendants, for the purpose of defrauding the Louisiana State Government, knowingly presented and/or caused to be presented false or fraudulent claims for payment or approval under Medicaid

and other Louisiana State funded programs within the meaning of La. Rev. Stat. 46:438.3(A).

249. As a result, Louisiana State monies were lost through payments made in respect of the claims and other costs were sustained by the Louisiana State Government.

250. Therefore, the Louisiana State Government has been damaged in an amount to be proven at trial.

251. Additionally, the Louisiana State Government is entitled to the maximum civil fine in the amount of three times the amount of actual damages sustained by the medical assistance programs as a result of the violations described herein. La. Rev. Stat. 46:438.6(B)(2).

TWENTY-SECOND CAUSE OF ACTION
(Louisiana Medical Assistance Programs Integrity Law
La. Rev. Stat. 46:438.3(B))

252. Plaintiff/relator repeats and realleges each and every allegation contained in paragraphs 1 through 125 above as though fully set forth herein.

253. This is a claim for a fine and damages under the Louisiana Medical Assistance Programs Integrity Law.

254. By virtue of the acts described above, Defendants, for the purpose of defrauding the Louisiana State Government, knowingly engaged in misrepresentations to obtain, or attempt to obtain, payment from medical assistance program funds within the meaning of La. Rev. Stat. 46:483.3(B).

255. As a result, Louisiana State monies were lost through payments made in respect of the defendants' conduct and other costs were sustained by the Louisiana State Government.

256. Therefore, the Louisiana State Government has been damaged in an amount to be proven at trial.

257. Additionally, the Louisiana State Government is entitled to the maximum civil fine in the amount of three times the amount of actual damages sustained by the medical assistance programs as a result of the violations described herein. La. Rev. Stat. 46:438.6(B)(2).

TWENTY-THIRD CAUSE OF ACTION
(Massachusetts False Claims Act
Mass. Gen. L. Ch. 12, §§ 5B(1))

258. Plaintiff/relator repeats and realleges each and every allegation contained in paragraphs 1 through 125 above as though fully set forth herein.

259. This is a claim for penalties and treble damages under the Massachusetts False Claims Act.

260. By virtue of the acts described above, Defendants, for the purpose of defrauding the Massachusetts Commonwealth Government, knowingly presented and/or caused to be presented false or fraudulent claims for payment or approval under Medicaid and other Massachusetts Commonwealth funded programs within the meaning of Mass. Gen. L. Ch. 12, §§ 5B(1).

261. As a result, Massachusetts Commonwealth monies were lost through payments made in respect of the claims and other costs were sustained by the Massachusetts Commonwealth Government.

262. Therefore, the Massachusetts Commonwealth Government has been damaged in an amount to be proven at trial.

263. Additionally, the Massachusetts Commonwealth Government is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim presented and caused to be presented by Defendants and arising from their fraudulent conduct as described herein.

TWENTY-FOURTH CAUSE OF ACTION
(Massachusetts False Claims Act
Mass. Gen. L. Ch. 12, §§ 5B(2))

264. Plaintiff/relator repeats and realleges each and every allegation contained in paragraphs 1 through 125 above as though fully set forth herein.

265. This is a claim for penalties and treble damages under the Massachusetts False Claims Act.

266. By virtue of the acts described above, Defendants, for the purpose of defrauding the Massachusetts Commonwealth Government, knowingly made, used, and/or caused to be made or used, false records or statements to obtain payment or approval of claims by the Commonwealth within the meaning of Mass. Gen. L. Ch. 12, §§ 5B(2).

267. As a result, Massachusetts Commonwealth monies were lost through payments made in respect of the claims and other costs were sustained by the Massachusetts Commonwealth Government.

268. Therefore, the Massachusetts Commonwealth Government has been damaged in an amount to be proven at trial.

269. Additionally, the Massachusetts Commonwealth Government is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim paid or approved arising from the Defendants' fraudulent conduct as described herein.

TWENTY-FIFTH CAUSE OF ACTION
(Michigan Medicaid False Claims Act
Mich. Comp. Laws § 400.610a)

270. Plaintiff/relator repeats and realleges each and every allegation contained in paragraphs 1 through 125 above as though fully set forth herein.

271. This is a claim for damages and a civil penalty under the Michigan Medicaid False Claims Act.

272. By virtue of the acts described above, Defendants, for the purpose of defrauding the Michigan State Government, made or presented, or caused to be made or presented, to an employee or officer of the State of Michigan a claim under the social welfare act, Act No. 280 of the Public Acts of 1939, as amended, being sections 400.1 to 400.121 of the Michigan Compiled Laws, upon or against the State, knowing the claim to be false within the meaning of Mich. Comp. Law §§ 400.601 et seq.

273. As a result, Michigan State monies were lost through payments made in respect of the claims and other costs were sustained by the Michigan State Government.

274. Therefore, the Michigan State Government has been damaged in an amount to be proven at trial.

275. Additionally, the Michigan State Government is entitled to a civil penalty equal to the full amount of the benefit received by the Defendants plus triple the amount of damages suffered by the state as a result of the conduct by Defendants as described herein.

TWENTY-SIXTH CAUSE OF ACTION
(Nevada False Claims Act
Nev. Rev. Stat. § 357.040(1)(a))

276. Plaintiff/relator repeats and realleges each and every allegation contained in paragraphs 1 through 125 above as though fully set forth herein.

277. This is a claim for penalties and treble damages under the Nevada False Claims Act, entitled “Submission of False Claims to State or Local Government”.

278. By virtue of the acts described above, Defendants, for the purpose of defrauding the Nevada State Government, knowingly presented and/or caused to be presented false claims for payment or approval under Medicaid and other Nevada State funded programs within the meaning of Nev. Rev. Stat. § 357.040(1)(a).

279. As a result, Nevada State monies were lost through payments made in respect of the claims and other costs were sustained by the Nevada State Government.

280. Therefore, the Nevada State Government has been damaged in an amount to be proven at trial.

281. Additionally, the Nevada State Government is entitled to the maximum penalty of $10,000 for each and every false claim presented and caused to be presented by Defendants and arising from their fraudulent conduct as described herein.

TWENTY-SEVENTH CAUSE OF ACTION
(Nevada False Claims Act
Nev. Rev. Stat. § 357.040(1)(b))

282. Plaintiff/relator repeats and realleges each and every allegation contained in paragraphs 1 through 125 above as though fully set forth herein.

283. This is a claim for penalties and treble damages under the Nevada False Claims Act, entitled “Submission of False Claims to State or Local Government”.

284. By virtue of the acts described above, Defendants, for the purpose of defrauding the Nevada State Government, knowingly made, used, and/or caused to be made or used, false records or statements to get false claims paid or

approved under Medicaid and other Nevada State funded programs within the meaning of Nev. Rev. Stat. § 357.040(1)(b).

285. As a result, Nevada State monies were lost through payments made in respect of the claims and other costs were sustained by the Nevada State Government.

286. Therefore, the Nevada State Government has been damaged in an amount to be proven at trial.

287. Additionally, the Nevada State Government is entitled to the maximum penalty of $10,000 for each and every false claim paid or approved arising from the Defendants' fraudulent conduct as described herein.

TWENTY-EIGHTH CAUSE OF ACTION
(New Hampshire False Claims Act
N.H. Rev. Stat. Ann. § 167:61-b(I)(a))

288. Plaintiff/relator repeats and realleges each and every allegation contained in paragraphs 1 through 125 above as though fully set forth herein.

289. This is a claim for penalties and treble damages under the New Hampshire False Claims Act.

290. By virtue of the acts described above, Defendants, for the purpose of defrauding the New Hampshire State Government, knowingly presented and/or caused to be presented false claims for payment or approval under Medicaid and other New Hampshire State funded programs to officers or employees of the state within the meaning of N.H. Rev. Stat. Ann. § 167:61-b(I)(a).

291. As a result, New Hampshire state monies were lost through payments made in respect of the claims and other costs were sustained by the New Hampshire State Government.

292. Therefore, the New Hampshire State Government has been damaged in an amount to be proven at trial.

293. Additionally, the New Hampshire State Government is entitled to the maximum penalty of $10,000 for each and every false claim presented and caused to be presented by Defendants and arising from their fraudulent conduct as described herein.

TWENTY-NINTH CAUSE OF ACTION
(New Hampshire False Claims Act
N.H. Rev. Stat. Ann. § 167:61-b(I)(b))

294. Plaintiff/relator repeats and realleges each and every allegation contained in paragraphs 1 through 125 above as though fully set forth herein.

295. This is a claim for penalties and treble damages under the New Hampshire False Claims Act.

296. By virtue of the acts described above, Defendants, for the purpose of defrauding the New Hampshire State Government, knowingly made, used, and/or caused to be made or used, false records or statements to get false claims paid or approved under Medicaid and other New Hampshire State funded programs within the meaning of N.H. Rev. Stat. Ann. § 167:61-b(I)(b).

297. As a result, New Hampshire State monies were lost through payments made in respect of the claims and other costs were sustained by the New Hampshire State Government.

298. Therefore, the New Hampshire State Government has been damaged in an amount to be proven at trial.

299. Additionally, the New Hampshire State Government is entitled to the maximum penalty of $10,000 for each and every false claim paid or approved arising from the Defendants' fraudulent conduct as described herein.

THIRTIETH CAUSE OF ACTION
(New Mexico Medicaid False Claims Act
N.M. Stat. Ann. § 27-14-4(A))

300. Plaintiff/relator repeats and realleges each and every allegation contained in paragraphs 1 through 125 above as though fully set forth herein.

301. This is a claim for penalties and treble damages under the New Mexico Medicaid False Claims Act.

302. By virtue of the acts described above, Defendants, for the purpose of defrauding the New Mexico State Government, knowingly presented and/or caused to be presented false claims for payment under Medicaid and other New Mexico State funded programs to the State within the meaning of N.M. Stat. Ann. § 27-14-4(A).

303. As a result, New Mexico State monies were lost through payments made in respect of the claims and other costs were sustained by the New Mexico State Government.

304. Therefore, the New Mexico State Government has been damaged in an amount to be proven at trial.

305. Additionally, the New Mexico State Government is entitled to the maximum penalty for each and every false claim presented and caused to be

presented by Defendants and arising from their fraudulent conduct as described herein.

THIRTY-FIRST CAUSE OF ACTION
(New Mexico Medicaid False Claims Act
N.M. Stat. Ann. § 27-14-4(C))

306. Plaintiff/relator repeats and realleges each and every allegation contained in paragraphs 1 through 125 above as though fully set forth herein.

307. This is a claim for penalties and treble damages under the New Mexico Medicaid False Claims Act.

308. By virtue of the acts described above, Defendants, for the purpose of defrauding the New Mexico State Government, knowingly made, used, and/or caused to be made or used, false records or statements to get false claims paid or approved under Medicaid and other New Mexico State funded programs within the meaning of N.M. Stat. Ann. § 27-14-4(C).

309. As a result, New Mexico State monies were lost through payments made in respect of the claims and other costs were sustained by the New Mexico State Government.

310. Therefore, the New Mexico State Government has been damaged in an amount to be proven at trial.

311. Additionally, the New Mexico State Government is entitled to the maximum penalty for each and every false claim paid or approved arising from the Defendants' fraudulent conduct as described herein.

THIRTY-SECOND CAUSE OF ACTION
(New York False Claims Act
N.Y. State Fin. Law § 189(1)(a))

312. Plaintiff/relator repeats and realleges each and every allegation contained in paragraphs 1 through 125 above as though fully set forth herein.

313. This is a claim for penalties and treble damages under the New York False Claims Act.

314. By virtue of the acts described above, Defendants, for the purpose of defrauding the New York State Government, knowingly presented and/or caused to be presented false claims for payment or approval under Medicaid and other New York State funded programs to officers or employees or agents of the state within the meaning of N.Y. State Fin. Law § 189(1)(a).

315. As a result, New York State monies were lost through payments made in respect of the claims and other costs were sustained by the New York State Government.

316. Therefore, the New York State Government has been damaged in an amount to be proven at trial.

317. Additionally, the New York State Government is entitled to the maximum penalty of $12,000 for each and every false claim presented and caused to be presented by Defendants and arising from their fraudulent conduct as described herein.

THIRTY-THIRD CAUSE OF ACTION
(New York False Claims Act
N.Y. State Fin. Law § 189(1)(b))

318. Plaintiff/relator repeats and realleges each and every allegation contained in paragraphs 1 through 125 above as though fully set forth herein.

319. This is a claim for penalties and treble damages under the New York False Claims Act.

320. By virtue of the acts described above, Defendants, for the purpose of defrauding the New York State Government, knowingly made, used, and/or caused to be made or used, false records or statements to get false claims paid or approved under Medicaid and other New York State funded programs within the meaning of N.Y. State Fin. Law § 189(1)(b).

321. As a result, New York State monies were lost through payments made in respect of the claims and other costs were sustained by the New York State Government.

322. Therefore, the New York State Government has been damaged in an amount to be proven at trial.

323. Additionally, the New York State Government is entitled to the maximum penalty of $12,000 for each and every false claim paid or approved arising from the Defendants' fraudulent conduct as described herein.

THIRTY-FOURTH CAUSE OF ACTION
(Tennessee False Claims Act
Tenn. Code Ann. § 4-18-103(a)(1))

324. Plaintiff/relator repeats and realleges each and every allegation contained in paragraphs 1 through 125 above as though fully set forth herein.

325. This is a claim for penalties and treble damages under the Tennessee False Claims Act.

326. By virtue of the acts described above, Defendants, for the purpose of defrauding the Tennessee State Government, knowingly presented and/or caused to be presented false claims for payment or approval under Medicaid and other

Tennessee State funded programs to officers or employees of the state within the meaning of Tenn. Code Ann. § 4-18-103(a)(1).

327. As a result, Tennessee State monies were lost through payments made in respect of the claims and other costs were sustained by the Tennessee State Government.

328. Therefore, the Tennessee State Government has been damaged in an amount to be proven at trial.

329. Additionally, the Tennessee State Government is entitled to the maximum penalty of $10,000 for each and every false claim presented and caused to be presented by Defendants and arising from their fraudulent conduct as described herein.

THIRTY-FIFTH CAUSE OF ACTION
(Tennessee False Claims Act
Tenn. Code Ann. § 4-18-103(a)(2))

330. Plaintiff/relator repeats and realleges each and every allegation contained in paragraphs 1 through 125 above as though fully set forth herein.

331. This is a claim for penalties and treble damages under the Tennessee False Claims Act.

332. By virtue of the acts described above, Defendants, for the purpose of defrauding the Tennessee State Government, knowingly made, used, and/or caused to be made or used, false records or statements to get false claims paid or approved under Medicaid and other Tennessee State funded programs within the meaning of Tenn. Code Ann. § 4-18-103(a)(2).

333. As a result, Tennessee State monies were lost through payments made in respect of the claims and other costs were sustained by the Tennessee State Government.

334. Therefore, the Tennessee State Government has been damaged in an amount to be proven at trial.

335. Additionally, the Tennessee State Government is entitled to the maximum penalty of $10,000 for each and every false claim paid or approved arising from the Defendants' fraudulent conduct as described herein.

THIRTY-SIXTH CAUSE OF ACTION
(Tennessee Medicaid False Claims Act
Tenn. Code Ann. § 71-5-182(a)(1)(A))

336. Plaintiff/relator repeats and realleges each and every allegation contained in paragraphs 1 through 125 above as though fully set forth herein.

337. This is a claim for penalties and treble damages under the Tennessee Medicaid False Claims Act.

338. By virtue of the acts described above, Defendants, for the purpose of defrauding the Tennessee State Government, knowingly presented and/or caused to be presented to the state claims for payment under the Medicaid program knowing such claims were false or fraudulent within the meaning of Tenn. Code Ann. § 71-5-182(a)(1)(A).

339. As a result, Tennessee State monies were lost through payments made in respect of the claims and other costs were sustained by the Tennessee State Government.

340. Therefore, the Tennessee State Government has been damaged in an amount to be proven at trial.

341. Additionally, the Tennessee State Government is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim presented and caused to be presented by Defendants and arising from their fraudulent conduct as described herein.

THIRTY-SEVENTH CAUSE OF ACTION
(Tennessee Medicaid False Claims Act
Tenn. Code Ann. § 71-5-182(a)(1)(B))

342. Plaintiff/relator repeats and realleges each and every allegation contained in paragraphs 1 through 125 above as though fully set forth herein.

343. This is a claim for penalties and treble damages under the Tennessee Medicaid False Claims Act.

344. By virtue of the acts described above, Defendants, for the purpose of defrauding the Tennessee State Government, knowingly made, used, and/or caused to be made or used, records or statements to get false or fraudulent claims under the Medicaid program paid for or approved by the state knowing such record or statement were false within the meaning of Tenn. Code Ann. § 71-5-182(a)(1)(B).

345. As a result, Tennessee State monies were lost through payments made in respect of the claims and other costs were sustained by the Tennessee State Government.

346. Therefore, the Tennessee State Government has been damaged in an amount to be proven at trial.

347. Additionally, the Tennessee State Government is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim paid or approved arising from the Defendants' fraudulent conduct as described herein.

THIRTY-EIGHTH CAUSE OF ACTION
(Texas Medicaid Fraud Prevention Law
Tex. Hum. Res. Code § 36.002(1)(A))

348. Plaintiff/relator repeats and realleges each and every allegation contained in paragraphs 1 through 125 above as though fully set forth herein.

349. This is a claim for restitution, interest, penalties and double damages under the Medicaid Fraud Prevention Law.

350. By virtue of the acts described above, the Defendants, for the purpose of defrauding the Texas State Government, knowingly or intentionally made, and/or caused to be made, false statements or representations of material facts on applications for contracts, benefits, or payments under the Medicaid program, within the meaning of Tex. Hum. Res. Code § 36.002(1)(A).

351. As a result, Texas State monies were lost through payments made in respect of the false statements or representations and other costs were sustained by the Texas State Government.

352. Therefore, the Texas State Government has been damaged in an amount to be proven at trial.

353. Additionally, the Texas State Government is entitled to the maximum penalty of $10,000 for each and every unlawful act committed by the Defendants under this provision. Tex. Hum. Res. Code § 36.052(3)(B).

THIRTY-NINTH CAUSE OF ACTION
(Texas Medicaid Fraud Prevention Law
Tex. Hum. Res. Code § 36.002(4)(B))

354. Plaintiff/relator repeats and realleges each and every allegation contained in paragraphs 1 through 125 above as though fully set forth herein.

355. This is a claim for restitution, interest, penalties and double damages under the Medicaid Fraud Prevention Law.

356. By virtue of the acts described above, the Defendants, for the purpose of defrauding the Texas State Government, knowingly or intentionally made, caused to be made, induced, and/or sought to induce, the making of false statements or misrepresentations of material fact concerning information required to be provided by a federal or state law, rule, regulation, or provider agreement pertaining to the Medicaid program, within the meaning of Tex. Hum. Res. Code § 36.002(4)(B).

357. As a result, Texas State monies were lost through payments made in respect of the false statements or representations and other costs were sustained by the Texas State Government.

358. Therefore, the Texas State Government has been damaged in an amount to be proven at trial.

359. Additionally, the Texas State Government is entitled to the maximum penalty of $10,000 for each and every unlawful act committed by the Defendants under this provision. Tex. Hum. Res. Code § 36.052(3)(B).

FORTIETH CAUSE OF ACTION
(Virginia Fraud Against Taxpayers Act
Va. Code Ann. § 8.01-216.3(A)(1))

360. Plaintiff/relator repeats and realleges each and every allegation contained in paragraphs 1 through 125 above as though fully set forth herein.

361. This is a claim for penalties and treble damages under the Virginia Fraud Against Taxpayers Act.

362. By virtue of the acts described above, Defendants, for the purpose of defrauding the Virginia Commonwealth Government, knowingly presented and/or caused to be presented false or fraudulent claims for payment or approval under Medicaid and other Virginia Commonwealth funded programs to officers or

employees of the Commonwealth within the meaning of Va. Code Ann. § 8.01-216.3(A)(1).

363. As a result, Virginia Commonwealth monies were lost through payments made in respect of the claims and other costs were sustained by the Virginia Commonwealth Government.

364. Therefore, the Virginia Commonwealth Government has been damaged in an amount to be proven at trial.

365. Additionally, the Virginia Commonwealth Government is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim presented and caused to be presented by Defendants and arising from their fraudulent conduct as described herein.

FORTY-FIRST CAUSE OF ACTION
(Virginia Fraud Against Taxpayers Act
Va. Code Ann. § 8.01-216.3(A)(2))

366. Plaintiff/relator repeats and realleges each and every allegation contained in paragraphs 1 through 125 above as though fully set forth herein.

367. This is a claim for penalties and treble damages under the Virginia Fraud Against Taxpayers Act.

368. By virtue of the acts described above, Defendants, for the purpose of defrauding the Virginia Commonwealth Government, knowingly made, used, and/or caused to be made or used, false records or statements to get false or fraudulent claims paid or approved by the Commonwealth under Medicaid and other Virginia Commonwealth funded programs within the meaning of Va. Code Ann. § 8.01-216.3(A)(2).

369. As a result, Virginia Commonwealth monies were lost through payments made in respect of the claims and other costs were sustained by the Virginia Commonwealth Government.

370. Therefore, the Virginia Commonwealth Government has been damaged in an amount to be proven at trial.

371. Additionally, the Virginia Commonwealth Government is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim paid or approved arising from the Defendants' fraudulent conduct as described herein.

FORTY-SECOND CAUSE OF ACTION
(Chicago False Claims Act
Chicago Mun. Code ch. 1-22-020(1))

372. Plaintiff/relator repeats and realleges each and every allegation contained in paragraphs 1 through 125 above as though fully set forth herein.

373. This is a claim for penalties and treble damages under the Chicago False Claims Act.

374. By virtue of the acts described above, Defendants, for the purpose of defrauding the Chicago City Government, knowingly presented and/or caused to be presented false claims for payment or approval under Medicaid and other Chicago City funded programs to officers or employees of the City within the meaning of Chicago Mun. Code ch. 1-22-020(1).

375. As a result, Chicago City monies were lost through payments made in respect of the claims and other costs were sustained by the Chicago City Government.

376. Therefore, the Chicago City Government has been damaged in an amount to be proven at trial.

377. Additionally, the Chicago City Government is entitled to the maximum penalty of $10,000 for each and every false claim presented and caused to be presented by Defendants and arising from their fraudulent conduct as described herein.

FORTY-THIRD CAUSE OF ACTION
(Chicago False Claims Act
Chicago Mun. Code ch. 1-22-020(2))

378. Plaintiff/relator repeats and realleges each and every allegation contained in paragraphs 1 through 125 above as though fully set forth herein.

379. This is a claim for penalties and treble damages under the Chicago False Claims Act.

380. By virtue of the acts described above, Defendants, for the purpose of defrauding the Chicago City Government, knowingly made, used, and/or caused to be made or used, false records or statement to get false claims paid or approved under Medicaid and other Chicago City funded programs within the meaning of Chicago Mun. Code ch. 1-22-020(2).

381. As a result, Chicago City monies were lost through payments made in respect of the claims and other costs were sustained by the Chicago City Government.

382. Therefore, the Chicago City Government has been damaged in an amount to be proven at trial.

383. Additionally, the Chicago City Government is entitled to the maximum penalty of $10,000 for each and every false claim presented and caused to be

presented by Defendants and arising from their fraudulent conduct as described herein.

DEMAND FOR RELIEF

WHEREFORE, Plaintiff prays for the following relief:

384. Judgment in an amount equal to threefold the damages to be proven at trial against Defendants and in favor of the United States, plus a civil penalty of up to $11,000 for each violation of 31 U.S.C. § 3729 proven at trial;

385. Judgment in an amount equal to threefold the damages to be proven at trial against Defendants and in favor of the State of California, plus a civil penalty of $10,000 for each violation of Cal. Gov't Code § 12651 proven at trial;

386. Judgment in an amount equal to threefold the damages to be proven at trial against Defendants and in favor of the State of Delaware, plus a civil penalty of $11,000 for each violation of 6 Del. C. § 1201 proven at trial;

387. Judgment in an amount equal to threefold the damages to be proven at trial against Defendants and in favor of the District of Columbia, plus a civil penalty of $10,000 for each violation of D.C. Code Ann. § 2-308.14 proven at trial;

388. Judgment in an amount equal to threefold the damages to be proven at trial against Defendants and in favor of the State of Florida, plus a civil penalty of $10,000 for each violation of Fla. Stat. Ann. § 68.082 proven at trial;

389. Judgment in an amount equal to threefold the damages to be proven at trial against Defendants and in favor of the State of Georgia, plus a civil penalty of $11,000 for each violation of Ga. Code Ann. § 49-4-168.1 proven at trial;

390. Judgment in an amount equal to threefold the damages to be proven at trial against Defendants and in favor of the State of Hawaii, plus a civil penalty of $10,000 for each violation of Haw. Rev. Stat. § 661-21 proven at trial;

391. Judgment in an amount equal to threefold the damages to be proven at trial against Defendants and in favor of the State of Illinois, plus a civil penalty of $10,000 for each violation of 740 Ill. Comp. Stat. § 175/3 proven at trial;

392. Judgment in an amount equal to threefold the damages to be proven at trial against Defendants and in favor of the State of Indiana, plus a civil penalty of at least $5,000 for each violation of Ind. Code § 5-11-5.5-2(b) proven at trial;

393. Judgment in an amount equal to the damages to be proven at trial against Defendants and in favor of the State of Louisiana, plus a civil fine in the amount

of three times the amount of actual damages sustained for each violation of La. Rev. Stat. 46:438.3 proven at trial;

394. Judgment in an amount equal to threefold the damages to be proven at trial against Defendants and in favor of the Commonwealth of Massachusetts, plus a civil penalty of $10,000 for each violation of Mass. Gen. L. Ch. 12, § 5B proven at trial;

395. Judgment in an amount equal to the damages to be proven at trial against Defendants and in favor of the State of Michigan, plus a civil penalty equal to the full amount of the benefit received by the Defendants plus triple the amount of damages suffered by the state for each violation of Mich. Comp. Laws § 400.610a proven at trial;

396. Judgment in an amount equal to threefold the damages to be proven at trial against Defendants and in favor of the State of Nevada, plus a civil penalty of $10,000 for each violation of Nev. Rev. Stat. Ann. §§ 357.040 proven at trial;

397. Judgment in an amount equal to threefold the damages to be proven at trial against Defendants and in favor of the State of New Hampshire, plus a civil penalty of $10,000 for each violation of N.H. Rev. Stat. Ann. § 167:61-b(I) proven at trial;

398. Judgment in an amount equal to threefold the damages to be proven at trial against Defendants and in favor of the State of New Mexico, plus a civil penalty for each violation of N.M. Stat. Ann. § 27-14-4 proven at trial;

399. Judgment in an amount equal to threefold the damages to be proven at trial against Defendants and in favor of the State of New York, plus a civil penalty of $12,000 for each violation of N.Y. State Fin. Law § 189 proven at trial;

400. Judgment in an amount equal to threefold the damages to be proven at trial against Defendants and in favor of the State of Tennessee, plus a civil penalty of $10,000 for each violation of Tenn. Code Ann. § Tenn. Code Ann. § 4-18-103 proven at trial;

401. Judgment in an amount equal to threefold the damages to be proven at trial against Defendants and in favor of the State of Tennessee, plus a civil penalty of $10,000 for each violation of Tenn. Code Ann. § 71-5-182 proven at trial;

402. Judgment in an amount equal to restitution, interest, and twofold the damages to be proven at trial against Defendants and in favor of the State of Texas, plus a civil penalty of $10,000 for each violation of Tex. Hum. Res. Code Ann. §§ 36.002 proven at trial;

403. Judgment in an amount equal to threefold the damages to be proven at trial against Defendants and in favor of the Commonwealth of Virginia, plus a civil penalty of $10,000 for each violation of Va. Code Ann. § 8.01-216.3 proven at trial;

404. Judgment in an amount equal to threefold the damages to be proven at trial against Defendants and in favor of the City of Chicago, plus a civil penalty of $10,000 for each violation of Chicago Mun. Code ch. 1-22-020 proven at trial;

405. An award to Jeffrey Bierman of the maximum amount allowed pursuant to 31 U.S.C. § 3730(d) and equivalent provisions in the state statutes set forth above, including the costs and expenses of this action and reasonable attorneys' fees; and

406. Such other, further and different relief, whether preliminary or permanent, legal or equitable, as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiff demands that his claims for relief against the Defendant be tried by a jury to the full extent permitted by law.

DATED: June 11, 2010

Respectfully submitted,

GETNICK & GETNICK

By: /s/ NEIL V. GETNICK
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CERTIFICATE OF SERVICE

I, Neil V. Getnick, Esq., counsel for Qui Tam Plaintiff / Relator Jeffrey J. Bierman, hereby certify that, on June 11, 2010, I caused a copy of the foregoing to be filed by electronic means with the United States District Court for the District of Massachusetts using the CM/ECF system, which will send notification to counsel of record.

/s/ NEIL V. GETNICK
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